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The Patentability of Medical Products:
Identifying Responsibilities of
Pharmaceutical Corporations towards
the Right to Health

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PhD in Law

2019

The Patentability of Medical Products:
Identifying Responsibilities of
Pharmaceutical Corporations towards
the Right to Health

Marc André Stuhldreier

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fulfilment of the requirements for the
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Newcastle

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of Business and Law

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Abstract

Each year, billions of people lack adequate access to urgently required medicines, leading to unnecessary suffering and the loss of millions of lives from preventable conditions. One of the main causes of this situation is that individuals living in extreme poverty cannot afford the prices of essential medicines, and the health-care systems of poverty-ridden developing countries are incapable of providing the required medications to their population. Exclusive patent rights contribute to the severity of this situation by providing the legal frameworks which enable pharmaceutical corporations to charge exorbitant prices for their patented drugs. Therefore, the global introduction of the patentability of pharmaceutical products under the WTO's TRIPS Agreement constitutes one of the main threats to the realisation of the Right to Health in developing countries.

This thesis addresses conflicting provisions of the human right to health and patent rights under international trade agreements, scrutinising whether there exists a legal hierarchy between human rights and trade law, or whether there are moral reasons suggesting that one should be superior to the other. Identifying that currently a legal hierarchy cannot be established, but that moral reasons suggest the superior importance of human rights, this thesis addresses the justifiability of the current international patent regime.

The main findings of this thesis suggest that the current international patent regime cannot be regarded as justified; either from a human rights perspective, or within itself. It is therefore submitted, that the international patent system urgently requires to be changed with respect to its regulations on the patentability of medical products. This thesis then proposes that the international patent regime offers the distinct opportunity of implementing direct responsibilities of pharmaceutical patent holders as requirements for patentability within international trade law itself, for example by an amendment of the TRIPS Agreement. In presenting these possibilities, this thesis contributes a further dimension to ongoing debates about how the human rights responsibilities of the private business sector can be identified and effectively enforced.

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List of Abbreviations

ARV	Antiretroviral
CESCR	Committee on Economic, Social and Cultural Rights
CSR	Corporate social responsibility
DSU	Dispute Settlement Understanding
EC	European Communities
ECHR	European Convention on Human Rights
ECJ	European Court of Justice
ECOSOC	United Nations Economic and Social Council
ECtHR	European Court of Human Rights
EU	European Union
FDI	Foreign direct investment
FTA	Free trade agreement
HRC	United Nations Human Rights Council
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
IP	Intellectual property

IPT	Intellectual Property Rights in Transition (Project)
LDCs	Least-developed countries
MDGs	Millennium Development Goals
MFN	Most-Favoured-Nation
MSF	Médecins Sans Frontières
OHCHR	Office of the United Nations High Commissioner for Human Rights
PGC	Principle of Generic Consistency
R&D	Research and development
RTA	Regional trade agreement
SDGs	Sustainable Development Goals
TPP	Trans-Pacific Partnership
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
UNCTAD	United Nations Conference on Trade and Development
US	United States
WHO	World Health Organization
WTO	World Trade Organization

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Beginning in 2011, with an essay on the TRIPS Agreement for a module on International Intellectual Property Rights with Professor Achim Albrecht, as part of my Bachelor's degree at Westfälische Hochschule in Germany, my interest in the interrelation between patent rights and human rights has now culminated in the completion of my very own doctoral thesis. From the early stages of my focussing on this subject area, I felt strongly about the injustices created by international patent standards, particularly in respect to the enjoyment of the right to health in developing countries. Ultimately, my passion for this topic motivated me to conduct my own research, investigating these injustices, and seeking to contribute to mitigating the problems created by the international patent regime; a journey, however, which I could not have embarked on alone by myself. In this regard, I would like to acknowledge, and express my thanks to the wonderful people who supported me along the way.

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Declaration

I declare that the work contained in this thesis has not been submitted for any other award and that it is all my own work. I also confirm that this work fully acknowledges opinions, ideas and contributions from the work of others.

Any ethical clearance for the research in this thesis has been approved. Approval has been sought and granted by the Faculty of Business and Law Ethics Committee on 04 January 2016.

I declare that the Word Count of this Thesis is 84,809 words.

Name: Marc André Stuhldreier

Signature:

Date: 31 May 2019

Introduction

Of all the forms of inequality, injustice in health is the most shocking and the most inhuman because it often results in physical death.

– Dr Martin Luther King, Jr*

The Research Context

Despite living in a time that is characterised by distinct advancements in social, economic, and technological development, and vast amounts of available resources, billions of people suffer from poverty – with several hundred-millions living in extreme poverty – without the means of realising a life in dignity.¹ Poverty is both a result of and a condition for human rights violations,² and is regarded by the World Health Organization (WHO) as ‘the number one killer worldwide.’³ Globally, almost two billion people – or one third of the world’s population – lack adequate access to medicines.⁴ Because of the severe poverty, insufficient healthcare systems, and

* Munro D, ‘The 50th Anniversary of Dr. King’s Healthcare Quote’ *Forbes* (25 March 2016) <<https://www.forbes.com/sites/danmunro/2016/03/25/the-50th-anniversary-of-dr-kings-healthcare-quote/#52c591a930b5>> accessed 17 May 2019.

¹ Office of the United Nations High Commissioner for Human Rights (OHCHR), ‘Guiding Principles on Extreme Poverty and Human Rights’ (2012) UN Doc A/HRC/21/39 <https://www.ohchr.org/Documents/Issues/Poverty/A-HRC-21-39_en.pdf> accessed 20 April 2019, para 1; United Nations General Assembly (UNGA), ‘Transforming our world: the 2030 Agenda for Sustainable Development’ (21 October 2015) UN Doc A/RES/70/1, para 14; The World Bank, ‘Poverty’ <<https://www.worldbank.org/en/topic/poverty/overview>> accessed 20 April 2019.

² OHCHR (n 1) para 3.

³ World Health Organization (WHO), ‘Health and Sustainable Development: Key Health Trends’ (2002) WHO Doc WHO/HDE/HID/02.2 <<https://apps.who.int/iris/handle/10665/68755>> accessed 20 April 2019, 11.

⁴ Forman L, ‘From TRIPS-Plus to Rights Plus? Exploring Right to Health Impact Assessment of Trade-Related Intellectual Property Rights through the Thai Experience’ (2012) 7 *AJWH* 347, 350; Hunt P and others, *Neglected Diseases: A Human Rights Analysis* (WHO 2007) 33; Khosla R and Hunt P, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines: The Sexual and Reproductive Health Context* (University of Essex 2008) 2; Lee JY and Hunt P, ‘Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines’ (2012) 40 *J.L. Med. & Ethics* 220, 220.

generally heightened levels of disease burdens, it can be observed that in the developing world this situation is magnified, affecting half of the population in the poorest countries.⁵ As a result, it is estimated that each year ten million lives are lost due to the insufficient accessibility of medications.⁶ This is particularly devastating and unjust considering that the health conditions are treatable, and the deaths and suffering thereby preventable, but that those in need cannot access the required medications.⁷ While the inaccessibility of medicines is caused by a variety of reasons, including insufficient infrastructure and healthcare systems, it is commonly acknowledged that high drug prices are one of the main determinants, due to the restricted resources available to people living in poverty.⁸ And even when the poor can barely afford expensive medicines, these high expenses have detrimental impacts on other aspects of their lives, such as the means for acquiring food or investing in education for children, exposing affected families to further impoverishment.⁹

The Role of Pharmaceutical Patents

Today, it is widely accepted that the pricing of medicines is considerably influenced by the availability of pharmaceutical patents.¹⁰ In essence, a patent is an intellectual property (IP)¹¹ right awarded to an inventor, which provides its owner with exclusive rights over the production, sale and use of his/her invention for a specified period of time.¹² The pharmaceutical industry argues that these patent rights are required to

⁵ Forman L, 'From TRIPS-Plus to Rights Plus?' (n 4) 350; Hunt P and others, *Neglected Diseases* (n 4) 33; Sellin J, *Access to Medicines: The Interface between Patents and Human Rights. Does one size fit all?* (Intersentia 2014) 21.

⁶ Khosla R and Hunt P (n 4) 2; Lee JY and Hunt P (n 4) 220; Sellin J (n 5) p21.

⁷ Lee JY and Hunt P (n 4) 220; Sellin J (n 5) 23.

⁸ Hunt P and others, *Neglected Diseases* (n 4) 33; Forman L, 'From TRIPS-Plus to Rights Plus?' (n 4) 350.

⁹ cf. Forman L, 'From TRIPS-Plus to Rights Plus?' (n 4) 350.

¹⁰ Forman L, 'From TRIPS-Plus to Rights Plus?' (n 4) 351; Forman L, 'Trade Rules, Intellectual Property, and the Right to Health' (2007) 21 *Ethics & International Affairs* 337, 339.

¹¹ Historically, IP rights were further categorised as 'authors' and artists' rights', such as copyrights, and 'industrial property rights', the category to which patents belong. See thereto: Abbott FM, 'Intellectual Property Rights in World Trade' in Guzman AT and Sykes AO (eds), *Research Handbook in International Economic Law* (Edward Elgar Publishing 2007) 445.

¹² Cambridge Dictionary, 'Patent' <<https://dictionary.cambridge.org/dictionary/english/patent>> accessed 15 May 2019; Duhaime's Law Dictionary, 'Patent Definition' <<http://www.duhaime.org/LegalDictionary/P/Patent.aspx>> accessed 15 May 2019; Oxford Living Dictionary, 'Patent' <<https://en.oxforddictionaries.com/definition/patent>> accessed 15 May 2019; Waelde C and others, *Contemporary Intellectual Property: Law and Policy* (4th edn, OUP 2016) para 1.7.

recoup high-risk pharmaceutical research and development (R&D) investments.¹³ Furthermore, the prospect of high profits, provided by monopolistic market positions granted by patent rights, is supposed to enhance research incentives for the development of new medical products, thereby improving the treatability of diseases in the future.¹⁴

With the coming into effect of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995, patent rights were internationally harmonised, which established the current international patent regime.¹⁵ One of the basic principles introduced by the TRIPS Agreement's patent section requires that patents are made available for all products and processes without discrimination as to the field of technology, meaning that WTO member states – with the exceptions of least-developed countries (LDCs) – cannot exclude the patentability of pharmaceutical products.¹⁶ As a result, by restricting generic competition, the exclusive rights provided to patent holders increased the prices of medicines in many developing countries where pharmaceutical patents were not available prior to TRIPS.¹⁷ While patents may ultimately lead to an enhanced availability of new medicines in the future, it must be noted that even marginal rises of medicine prices can severely restrict their accessibility for the poor in developing countries.¹⁸ In 2001, the recognition of the detrimental impacts of pharmaceutical patent rights by the WTO led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration), which acknowledges that the TRIPS Agreement should be

¹³ Sellin J (n 5) 24.

¹⁴ cf. Abbott FM, 'Trade in Medicines' in Smith R and others (eds), *Trade and Health: Towards Building a National Strategy* (WHO 2015) 135; Abbott FM, 'Intellectual Property and Public Health: Meeting the Challenge of Sustainability' (2011) *Global Health Programme Working Paper No7/2011*, 9 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1965458> accessed 22 May 2019; Henry D and Searles A, 'Chapter 9: Pharmaceutical Pricing Policy' in *Management Sciences for Health, MDS-3: Managing Access to Medicines and Health Technologies* (3rd edn, Management Sciences for Health 2012) <<http://apps.who.int/medicinedocs/documents/s19577en/s19577en.pdf>> accessed 02 March 2019, 9.2 and 9.7; United Nations Economic and Social Council (ECOSOC), 'The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights' (27 June 2001) *Un Doc E/CN.4/Sub.2/2001/13*, para 11.

¹⁵ cf. Abbott FM, 'Intellectual Property Rights in World Trade' (n 11) 453; Forman L, 'Trade Rules' (n 10) 339.

¹⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (signed 15 April 1994, entered into force 1 January 1995) [TRIPS Agreement] Article 27; see thereto: Forman L, 'Trade Rules' (n 10) 339.

¹⁷ Forman L, 'Trade Rules' (n 10) 339; Hestermeyer H, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (OUP 2007) 78.

¹⁸ Hestermeyer H (n 17) 78; Sellin J (n 5) 23.

implemented in a manner conducive to public health.¹⁹ In this respect, the Doha Declaration provides that all WTO members have the right to make full use of the flexibilities and exceptions provided by the TRIPS Agreement to protect public health, particularly in situations of national emergencies or other circumstances of extreme urgency, which explicitly include public health crises.²⁰ The effectiveness of these protection mechanisms, however, is undermined by the fact that the TRIPS Agreement only provides minimum patent protection standards, leaving WTO members free to implement higher protection levels.²¹ This has led to the adoption of so-called TRIPS-Plus Agreements, which tend to further strengthen patent protection and introduce provisions that are designed to restrict the use of the flexibilities and exceptions provided by TRIPS, resulting in further detrimental impacts on the accessibility of medicines in developing countries.²²

In view of this situation, and considering that the accessibility of medicines is commonly regarded as an integral part of the human right to health,²³ it can be suggested that by limiting this accessibility, patent rights create severe obstacles for the realisation of human rights objectives. By potentially enhancing the future availability of new medicines, however, patents may provide future benefits for the enjoyment of the right to health. It is therefore suggested that to be justifiable, patent rights should be approached from a human rights perspective, which explicitly recognises the social function of patents.²⁴ Such an approach requires the establishment of an adequate balance between exclusive rights and responsibilities of patent holders. At the present time, however, such responsibilities are not sufficiently defined, either by international human rights law, or by the international patent regime.

¹⁹ World Trade Organization (WTO), 'Doha Declaration on the TRIPS Agreement and Public Health: Ministerial Declaration of 14 November 2001' (20 November 2001) WTO Doc WT/MIN(01)/DEC/2 [Doha Declaration].

²⁰ Doha Declaration (n 19) paras 4 and 5.

²¹ TRIPS Agreement (n 16) Article 1(1).

²² Frankel S, 'Challenging TRIPS-Plus Agreements: The Potential Utility of Non-Violation Disputes' (2009) 12 JIEL 1023, 1025; Ho CM, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 225.

²³ cf. Lee JY and Hunt P (n 4) 220.

²⁴ Sell SK, 'TRIPS-Plus Free Trade Agreements and Access to Medicines' (2007) 28 Liverpool Law Review 41, 66.

The Purpose of this Thesis

Recognising the magnitude of the detrimental impacts created by the patentability of pharmaceutical products, the main objective of this thesis is the identification of responsibilities of pharmaceutical patent holders towards the right to health. The aim is then to propose improvements to the international patent regime in order to adequately balance private exclusive rights with the wider societal interest in public health. Thereby, patent laws could be brought into line with fundamental human rights objectives. It is important to note here that the detrimental impacts of the international patent regime are not limited to the patentability of medical products, and that further injustices arise in other areas – for example relating to the right to food, biodiversity, and the protection of traditional knowledge – which should be addressed by future revisions of the TRIPS Agreement as well. The analysis of these issues, however, exceeds the scope of this research, so that the proposals made in this thesis are primarily tailored to the specific issues arising from pharmaceutical patent rights.

For the purpose of this thesis, the terms ‘developing countries’ and ‘developing world’ shall be considered synonymously, commonly referring to low- and middle-income countries in the global South. While for WTO purposes, the categorisation of developing countries is generally based on how a country perceives itself, it is commonly estimated that around two-thirds of WTO member states are developing countries.²⁵ For the definition of ‘least-developed countries (LDCs)’, this thesis, as well as the WTO, follow the UN list of LDCs, which at the time of writing identifies 47 LDCs, 36 of which are members of the WTO.²⁶ The reference to developing countries or the developing world in this thesis always includes LDCs, while a direct reference to LDCs focusses on the specific issues faced by these countries. Furthermore, while occasionally drawing examples from certain countries, this thesis is not focussing on any specific developing country or LDC.

²⁵ Sellin J (n 5) 173.

²⁶ UNCTAD, ‘UN list of Least Developed Countries’
<<https://unctad.org/en/Pages/ALDC/Least%20Developed%20Countries/UN-list-of-Least-Developed-Countries.aspx>> accessed 16 May 2019; United Nations, ‘LDC list’
<<https://www.un.org/development/desa/dpad/least-developed-country-category/ldcs-at-a-glance.htm>> accessed 16 May 2019; WTO, ‘Least-developed countries’
<https://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm> accessed 16 May 2019.

Research Questions

In order to address the above elaborated issues arising from pharmaceutical patent rights, particularly concerning the realisation of the human right to health, this thesis scrutinises a number of interrelated Research Questions in the following order:

1. What is the relationship between international human rights law and international IP/trade law?
2. Are there valid moral principles that can be utilised to justify the prioritisation of the right to health over contradictory provisions of international trade law and patent law?
3. Recognising the importance of the right to health and access to medicines for human life in dignity, is the current international patent regime (under TRIPS and TRIPS-Plus) justified when the protection of private interests directly impacts on the affordability of medicines and public health?
 - 3.1. Do the aims and purposes of patents justify a short-term restriction of the accessibility of medicines?
 - 3.2. Do patents on pharmaceutical products actually fulfil their purposes and objectives?
4. Why is the corporate social responsibility approach of identifying the human rights responsibilities of the private business sector in non-binding international soft law instruments, insufficient for adequately regulating the pharmaceutical industry's conduct towards the right to health?
5. Can responsibilities of pharmaceutical patent holders towards the realisation of the right to health be implemented into the TRIPS Agreement in order to establish a balance between private interests and public health, thereby enhancing the justification of the international patent regime?

The Structure of this Thesis

To appropriately explore the issues created by pharmaceutical patent rights, the thesis is divided into two parts. Part I, consisting of chapters 1 and 2, applies descriptive and interpretative methods, elaborating on the underlying legal framework as relevant in the context of this thesis. To this end, chapter 1 provides an overview of the normative scope of the right to health and interrelated rights, under international human rights law. Adopting a hermeneutic approach, this chapter seeks to understand the

teleological purpose behind these the legal regulations, particularly aiming to establish whether the accessibility of medicines is encompassed by the right to health, and thereby protected under human rights law. The hermeneutic methodology is specifically applied to identify the implicit meaning of the legal provisions, going beyond their mere wording, seeking to provide an understanding of the purpose behind these regulations with particular regard to their intended aims and objectives.²⁷ The teleological analysis shall then further scrutinise how far the purpose of human rights law implies the existence of non-state actor responsibilities towards the right to health. Chapter 2 provides an overview of the current international patent regime, elaborating on the scope of patent rights as regulated under the WTO TRIPS Agreement, and TRIPS-Plus trade agreements. This chapter is predominantly descriptive in nature, outlining the content of the legal treaty texts, and conducting a literature review of relevant legal-political commentaries and interpretative academic scholarship. Thereby, this chapter aims to map out the functioning of international patent standards, and identify the potentially harmful consequences, inherent to the granting of imbalanced private exclusive rights. In summary, Part I depicts the factual situation, and provides an interpretation of the legal principles, underlying the descriptive analysis conducted in the second part of this thesis, which scrutinises the actual impacts of pharmaceutical patent rights on the realisation of the right to health.

Part II of this research, consisting of chapters 3 to 5, Part II adopts analytical methods, examining the justification and shortcomings of the international patent regime, in order to then propose improvements to the system, aiming to alleviate its detrimental impacts. Before addressing the justification of current patent standards in chapter 4, however, chapter 3 establishes the parameters against which this justification can be scrutinised. To this end, the first part of chapter 3 contemplates the existence of a legal hierarchy between the right to health under international human rights law, and patent rights under international intellectual property (IP) and trade law, by addressing Research Question 1:

What is the relationship between international human rights law and international IP/trade law?

²⁷ cf. Kinsella EA, 'Hermeneutics and Critical Hermeneutics: Exploring Possibilities within the Art of Interpretation' (2006) 7 Forum: Qualitative Social Research <<http://www.qualitative-research.net/index.php/fqs/article/view/145/319#gcit>> accessed 24 April 2019.

This analysis conducts a critical literature review of the legal-theoretical concepts and methods of treaty interpretation, reaffirming the current position that under international law different treaty regimes are functionally detached, so that a hierarchical structure between the right to health and patent laws cannot be established. Therefore, the second part of chapter 3 considers the applicability of non-legal considerations that may imply a hierarchy of rights based on moral-philosophical reasons. In this respect, Research Questions 2 asks:

Are there valid moral principles that can be utilised to justify the prioritisation of the right to health over contradictory provisions of international trade law and patent law?

This analysis elaborates on the concept of morality, focussing in particular on human dignity and human agency, applying an egalitarian ethical concept, in that all persons are regarded as being of equal worth. With reference to Gewirth's Principle of Generic Consistency (PGC), it is then established that all human agents have equal rights to the generic needs necessary for their agency. Based on Gewirth's needs based hierarchy, chapter 3 concludes by suggesting that the PGC can be utilised to justify a prioritisation of those human rights that are fundamental for the realisation and protection of human life and well-being, including the right to health, over less-essential rights.

In this respect, chapter 4 scrutinises the justification of the international patent regime, inter alia, against its compliance with the right to health, by addressing Research Question 3:

Recognising the importance of the right to health and access to medicines for human life in dignity, is the current international patent regime (under TRIPS and TRIPS-Plus) justified when the protection of private interests directly impacts on the affordability of medicines and public health?

By adopting a method of inductive reasoning, the answer to this question is deduced from two sub-questions. First, Sub-Question 3.1 analyses:

Do the aims and purposes of patents justify a short-term restriction of the accessibility of medicines?

To answer this question, the first part of this chapter adopts descriptive and evaluative methods, outlining the objectives and purposes of the international patent regime,

before evaluating legal-political and socio-economic reports, and empirical studies, to identify the detrimental impacts of pharmaceutical patents. The analysis indicates that it is not possible to provide a unanimously conclusive answer to Sub-Question 3.1. However, it is suggested that if any short-term restriction of the accessibility of medicines shall be justifiable at all, patent rights would need to be capable of adequately fulfilling their purposes. In this regard, Sub-Question 3.2 asks:

Do patents on pharmaceutical products actually fulfil their purposes and objectives?

This second part of chapter 4 adopts an evaluative approach, analysing secondary resources and impact reports, indicating that while the patent regime may fulfil some of its objectives, patent rights are by nature incapable of sufficiently fulfilling all their purposes. An answer to Research Question 3 is then deduced from the findings of Sub-Questions 3.1 and 3.2, determining that the current international patent regime is not justified. Chapter 4 further concludes that the shortcomings of international patent laws are, *inter alia*, attributable to the distinct lack of clear responsibilities of pharmaceutical patent holders, which could provide a counterbalance to the excessive exclusive rights granted by patent protection.

Based on the recognition that the detrimental impacts of the patentability of pharmaceutical products can be attenuated by the introduction of responsibilities of pharmaceutical patent holders, chapter 5 addresses the main objective of this thesis; the identification and implementation of responsibilities of the pharmaceutical industry towards the right to health. To this end, the first part of this chapter analyses existing approaches to the identification of corporate human rights responsibilities, which are traditionally implemented in non-binding soft law instruments, based on the concept of corporate social responsibility (CSR). Indicating that non-binding instruments are insufficient for alleviating the detrimental impacts of the international patent regime, Research Question 4 evaluates:

Why is the corporate social responsibility approach of identifying the human rights responsibilities of the private business sector in non-binding international soft law instruments, insufficient for adequately regulating the pharmaceutical industry's conduct towards the right to health?

This analysis suggests that the implications of the right to health on the lives and livelihood of human beings are of such magnitude that the adherence to responsibilities for its respect and protection must not be subject to the goodwill of corporations. In this regard, the second part of chapter 5 explores the possibility of implementing legally binding and enforceable responsibilities, addressing this thesis's determinative Research Question 5:

Can responsibilities of pharmaceutical patent holders towards the realisation of the right to health be implemented into the TRIPS Agreement in order to establish a balance between private interests and public health, thereby enhancing the justification of the international patent regime?

The answer to this question brings together the findings of this research, suggesting a theoretical but pragmatic concept of potential solutions to the elaborated problems. The analysis indicates that the very patentability of pharmaceutical products itself provides a unique opportunity for implementing enforceable responsibilities of pharmaceutical patent holders as direct obligations under international IP laws. After elaborating on the scope of this opportunity, chapter 5 concludes by proposing an amendment to the TRIPS Agreement, suggesting the introduction of distinct obligations, to counterbalance the exclusive rights granted to patent holders, thereby harmonising the protection of private and public interests while ensuring due regard for human rights.

Part I: The Legal Framework

Chapter One

1 The Human Rights Context

The patentability of pharmaceutical products provides private exclusive rights to patent holders, granting them monopolistic market positions with potential direct negative impacts on the realisation of the human right to health. It is therefore of crucial importance to identify the scope of the right to health in order to scrutinise whether the current international patent regime can be regarded as justified, and to identify specific responsibilities of pharmaceutical patent holders towards the protection of public health. As an in-depth examination of all the intricacies of the right to health exceeds the scope of this thesis, the following chapter only focusses on specific elements that are closely interconnected with the issues arising from pharmaceutical patent rights. To this end, the first section of this chapter provides an overview of the normative framework of the right to health. The second section briefly analyses the substantive content of the right to health by elaborating on the obligations of states as the main duty bearers under international human rights law, before considering whether non-state actors, such as private corporations, currently have responsibilities towards the realisation of public health, too. Lastly, the right to health is considered in the context of its interrelation with other human rights to indicate the importance of the protection of human health for the achievement of an adequate standard of living. In addition to providing an overview of the scope of the right to health, this chapter aims to reaffirm that the accessibility, and particularly the affordability of medicines constitutes an integral requirement for the realisation of the right to health.

1.1 The Normative Framework of the Right to Health

As with most human rights, the human right to health has its roots in the Universal Declaration on Human Rights (UDHR) which states in Article 25(1):

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.¹

This provision not only recognises the entitlement to a standard of living adequate for the health and well-being of everyone, but explicitly recognises medical care as a necessity for realising this standard of living. The UDHR was adopted in 1948 as a direct response to the atrocities committed by the Nazi regime during the Second World War.² The initial purpose of the declaration is therefore considered in the prevention of a repetition of such severe violations of basic human rights, which up until then were only scarcely recognised by international law.³ Nevertheless, the scope of the UDHR encompasses a wider variety of human rights, including political and civil rights, as well as certain economic and social rights.⁴ A main problem with the UDHR is that it was originally only intended to provide targets for the political commitment of governments, wherefore the declaration is commonly not regarded as being directly legally binding.⁵ In recognition of its longstanding acceptance throughout the world, however, it may be suggested that the UDHR now has become part of customary international law, implying a compulsory nature of the declaration.⁶ This is particularly relevant in context of the declaration's preamble, which recognises 'the dignity and the equal and inalienable rights of all members of the human family' as the 'foundation of freedom, justice and peace'.⁷ It is submitted that particularly the qualification 'inalienable' in its teleological sense promulgates a superiority of human

¹ UDHR The Universal Declaration on Human Rights (adopted 10 December 1948) [UDHR], Article 25(1)

² Michael Freeman, *Human Rights: An Interdisciplinary Approach* (2nd edn, Polity Press 2011) 38 and 41.

³ *ibid* 40-41.

⁴ *ibid* 42.

⁵ *ibid*; Woods K, *Human Rights* (Palgrave MacMillan 2014) 7.

⁶ Flinterman C, 'Human Rights Law Status Report' in Grosheide W (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar Publishing 2010) 38.

⁷ UDHR (n 1) Preamble.

rights above any other, contradicting provision. As elaborated in chapter 3.1.3, however, this concept of superiority is controversial, as international law lacks a clear hierarchical structure, so that different treaty regimes currently act independently from each other. Nevertheless, the global progress made towards the recognition and realisation of human rights in the past 70 years, since the adoption of the UDHR, indicates the declaration's unambiguous influence on political and legal policy commitments.⁸

The right to health is further recognised in several international conventions and declarations, including the International Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Elimination of All Forms of Discrimination against Women, the Convention of the Right of the Child, and the Vienna Declaration and Programme of Action.⁹ Similarly, the right to health is recognised by regional human rights documents, including the African Charter on Human and People's Rights.¹⁰ Notably, the right to health is not considered by the European Convention on Human Rights. It is, however, recognised by the European Social Charter, which states in Paragraph 11 of Part I:

Everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable.¹¹

Additionally, Article 35 of the EU Charter of Fundamental Freedoms provides an explicit right to healthcare.¹² The Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, furthermore not only recognises the right to health, but even goes a step further by defining it in Article 10(1) as a right to 'the enjoyment of the highest level of physical, mental and social

⁸ Freeman M (n 2) 42.

⁹ International Convention on the Elimination of All Forms of Racial Discrimination (adopted 21 December 1965, entered into force 4 January 1969), Article 5; Convention on the Elimination of All Forms of Discrimination against Women (adopted 18 December 1979, entered into force 3 September 1981), Articles 10, 11, 12, and 14; Convention on the Rights of the Child (adopted 20 November 1989, entered into force 2 September 1990), Articles 17, 23, 24, 25, 32, and 39; World Conference on Human Rights 14-25 June 1993, *Vienna Declaration and Programme of Action* (adopted 25 June 1993) Un Doc A/CONF.157/23, Articles 11, 18, 24, 31, and 41.

¹⁰ African Charter on Human and People's Rights (adopted 27 June 1981, entered into force 21 October 1986), Article 16.

¹¹ The European Social Charter (revised 3 May 1996, entered into force 1 July 1999), Part I Paragraph 11.

¹² Charter of Fundamental Rights of the European Union (ratified 7 December 2000), Article 35.

well-being.¹³ In Article 10(2), health is considered a public good and Article 10(2)(f) explicitly considers the high vulnerability and special protection needs of people living in poverty.¹⁴

Of the above-mentioned conventions, declarations, and other human rights documents, all but the UDHR and the Vienna Declaration and Programme of Action are either restricted by their geographical applicability, or by their applicability to only certain groups of people. For the purpose of this thesis, however, it is important to consider the right to health from a global perspective, applicable and valid for as many human beings as possible. In this consideration, the most comprehensive affirmation of the right to health is to be found in the International Covenant on Economic, Social and Cultural Rights (ICESCR). In contrast to the UDHR, the ICESCR is an international treaty which provides directly legally binding obligations on its member states.¹⁵ The covenant was adopted on 16 December 1966, entered into force on 3 January 1976, and, as of March 2019, 161 states are parties to the treaty.¹⁶ Addressing the right to health as a social human right, Article 12 ICESCR provides:

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
 - (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
 - (b) The improvement of all aspects of environmental and industrial hygiene;
 - (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
 - (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.¹⁷

¹³ Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (entered into force 16 November 1999), Article 10(1).

¹⁴ *ibid* Article 10(2).

¹⁵ ESCR-Net, 'Section 5: Background Information on the ICESCR' <<https://www.escri-net.org/resources/section-5-background-information-icescr>> accessed 13 March 2019.

¹⁶ United Nations Treaty Collection, 'International Covenant on Economic, Social and Cultural Rights' <https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=IV-3&chapter=4&clang=_en> accessed 13 March 2019.

¹⁷ International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) [ICESCR], Article 12.

1.2 Interpretation of the Right to Health

On 28 May 1985, the United Nations Economic and Social Council (ECOSOC) established the Committee on Economic, Social, and Cultural Rights (CESCR) as the official body to monitor the implementation of the ICESCR.¹⁸ One of the functions of this committee is the interpretation of the content of the ICESCR, clarifying the exact meaning of the provisions in the so-called General Comments.¹⁹ In respect of the right to the highest attainable standard of health provided by Article 12 ICESCR, the committee provides a detailed analysis of the scope and content of the provision in its General Comment No. 14, adopted at the 22nd Session of the CESCR held on 11 August 2000.²⁰ It is important to note that the CESCR General Comments are not acknowledged by all member states of the ICESCR and therefore cannot be regarded as legally binding documents, as further elaborated in chapter 3.1.1.2. The US, in particular, does not recognise the legal validity of General Comments, pointing to the lack of governmental involvement in their creation.²¹ Nevertheless, as the CESCR is established by a UN body, the General Comments are the most authoritative documents elaborating on the content of the ICESCR, so that these comments need to be considered as relevant for the interpretation of international human rights law.²²

The international community provides a number of related definitions of the term 'health'. For the purpose of this thesis, emphasis is given to CESCR General Comment No. 14, which defines health as 'a fundamental human right indispensable for the exercise of other human rights.'²³ Paragraph 1 further clarifies that '[e]very human being is entitled to the enjoyment of the highest attainable standard of health conducive

¹⁸ United Nations Economic and Social Council (ECOSOC), 'Review of the composition, organization and administrative arrangements of the Sessional Working Group of Governmental Experts on the Implementation of the International Covenant on Economic, Social and Cultural Rights' (28 May 1985) UN Doc E/RES/1985/17; Office of the United Nations High Commissioner for Human Rights (OHCHR), 'Committee on Economic, Social and Cultural Rights: Monitoring the economic, social and cultural rights' <<https://ohchr.org/EN/HRBodies/CESCR/Pages/CESCRIntro.aspx>> accessed 06/03/2019.

¹⁹ OHCHR (n 18).

²⁰ Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights)* (11 August 2000) UN Doc E/C.12/2000/4.

²¹ cf. Wolff J, *The Human Right to Health* (W. W. Norton & Company 2012) 31.

²² Mechlem K, 'Treaty Bodies and the Interpretation of Human Rights' (2009) 42 *Vanderbilt Journal of Transnational Law* 905, 929.

²³ CESCR, *General Comment No. 14* (n 20) para 1.

to living a life in dignity.’²⁴ This interpretation is in accordance with the constitution of the World Health Organisation (WHO) which defines in its preamble that ‘[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being [...]’.²⁵ Additionally, both the preamble of the WHO, as well as Article I of the Declaration of Alma-Ata, further define health as ‘a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity’.²⁶ The right to health, however, does not entail a right to be healthy,²⁷ as no person or institution can provide for and/or guarantee such an outcome. It has to be accepted that all human beings are vulnerable to falling ill.²⁸ Being affected by ill-health or a disease thus is an unfortunate happenstance, but commonly no one is at fault.²⁹

In this consideration, the right to health under Article 12 ICESCR rather demands the creation of circumstances under which ‘people can lead a healthy life’.³⁰ Article 25 UDHR further declares that a standard of living which is adequate for human health and well-being encompasses a right to medical care in the event of sickness.³¹ In this respect, both case law, as well as several UN Commission on Human Rights (OHCHR) resolutions reaffirm that access to essential medicines is an integral part of the right to health.³² Similarly, Section (d) of the preamble of Paul Hunt’s Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines determines medical care and access to medicines as a ‘vital feature of the right to the highest attainable standard of health’.³³ Paul Farmer therefore suggests that denying access to adequate medical care amounts to a violation of economic and social human

²⁴ *ibid.*

²⁵ Constitution of the World Health Organization (adopted 22 July 1946, entered into force 7 April 1948), Preamble.

²⁶ International Conference on Primary Health Care, *Declaration of Alma-Ata* (adopted 6-12 September 1978) [Declaration of Alma-Ata], Article I; Similarly expressed in the Preamble of the Constitution of the World Health Organization (n 25), with the only difference that ‘wellbeing’ is written with a hyphen in the Constitution of the WHO, i.e. ‘well-being’.

²⁷ CESCR, *General Comment No. 14* (n 20) para 8.

²⁸ Wolff J (n 21) 27.

²⁹ *ibid* 1.

³⁰ CESCR, *General Comment No. 14* (n 20) para 4.

³¹ UDHR (n 1) Article 25.

³² Khosla R and Hunt P, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines: The Sexual and Reproductive Health Context* (University of Essex 2008) 2 and 3.

³³ Hunt P, ‘Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines’ (11 August 2008) in the Annex to the ‘Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’, United Nations General Assembly, UN Doc A/63/263, Preamble para (d).

rights.³⁴ As will be elaborated in the next section, it is submitted that allowing the existence of obstacles to the accessibility of medicines is a violation of a state's obligation to protect and fulfil the right to health, wherefore such an omission can be construed as denying access.

1.2.1 Obligations of States

As a comprehensive analysis of all the intricacies of the right to health exceeds the scope of this research, the following sections focus on providing a brief outline of some of the key regulations and interpretations as relevant in regard to the patentability of pharmaceutical products addressed in this thesis. After Article 12(1) ICESCR declares the right to health as a human right, Article 12(2) provides a non-exhaustive list of state obligations that shall facilitate the realisation of equal opportunities for everyone to enjoy 'the highest attainable standard of health.'³⁵ The realisation of the right to health, inter alia, demands the timely provision of appropriate healthcare goods and services.³⁶ For the scope of this thesis, it is emphasised that the appropriate provision of health-care goods and services requires states to ensure that medical products are available and accessible to all people, as elaborated below in 1.2.1.1. It is submitted that the 'timely provision' requirement further demands that new medications are made available at affordable prices, as soon as reasonably possible.

As with most human rights, states are the main duty bearers with regard to ensuring the enjoyment of the right to health. In particular, states have three main obligations towards the realisation of the right to health, namely the obligations to respect, to protect and to fulfil the right to health.³⁷ The obligation to respect demands that states refrain from interfering with the enjoyment of the right to health, for example, by limiting or denying equal access to healthcare, or by performing discriminatory practices.³⁸ The obligation to protect requires the implementation of legislation and other measures, ensuring equal access to medical treatment and preventing third parties

³⁴ Farmer P, *Pathologies of Power: Health, Human Rights, and the New War on the Poor* (University of California Press 2004) 253.

³⁵ CESCR, *General Comment No. 14* (n 20) para 8; See also: CESCR, *General Comment No. 14* (n 20) para 7.

³⁶ *ibid* para 11.

³⁷ *ibid* para 33.

³⁸ *ibid* paras 33 and 34.

from interfering with the enjoyment of the right to health.³⁹ The obligation to fulfil requires states to pay due regard to the right to health in domestic policies and legislation, demanding inter alia the adoption of a detailed national health policy.⁴⁰ Fulfilment further encompasses the direct provision of essential medicines to people living in poverty who otherwise cannot access such medications.⁴¹ According to the Maastricht Guidelines, a state's failure to meet any of the three main obligations constitutes a violation of the ICESCR and therefore of the right to health.⁴²

It is important to realise that while states are mandated to do what they can, it would be unreasonable to require states to accomplish the impossible. Therefore, the determination of the highest attainable standard of health in a given situation requires the consideration of a state's available resources, as well as biological and socio-economic circumstances of individuals.⁴³ As elaborated below in 1.2.1.3, the obligations of states towards the right to health are subject to progressive realisation, with certain core obligations which always need to be performed.

1.2.1.1 Availability and Accessibility

The right to health consists of four main elements, namely the availability, the accessibility, the acceptability, and the quality of health care facilities, goods and services.⁴⁴ The elements of acceptability and quality are predominantly appropriateness requirements in that they demand that all health-care facilities, goods and services must be appropriate in regard to medical ethics, cultural demands, and their medical quality.⁴⁵ In respect of the interrelation of the right to health and the international patent regime, the elements of availability and accessibility in particular are of crucial importance for the scope of this thesis.

³⁹ *ibid* paras 33 and 35.

⁴⁰ *ibid* para 36.

⁴¹ *ibid* para 37; Hunt P, 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (13 September 2006) United Nations General Assembly, UN Doc A/61/338, para 59.

⁴² International Commission of Jurists (ICJ), *Maastricht Guidelines on Violations of Economic, Social and Cultural Rights* (26 January 1997), Guideline 6.

⁴³ CESCR, *General Comment No. 14* (n 20) para 9.

⁴⁴ *ibid* para 12.

⁴⁵ *ibid* paras 12(c) and 12(d).

In general, the availability requirement simply demands the existence or creation of health-care facilities, programmes, goods and services in sufficient quantities.⁴⁶ In reference to the notion of health-care goods, it can be established that the realisation of the right to health requires the adequate availability of medicines, and particularly essential drugs.⁴⁷ To achieve this, states are inter alia encouraged to make use of the flexibilities granted by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), for example by utilising compulsory license legislation, as elaborated in chapters 2.4.3.7 and 2.4.3.8, to alleviate detrimental impacts of pharmaceutical patents and ensure that medicines are available in sufficient quantities.⁴⁸ The element of availability, however, not only concerns the availability of existing medications, but further entails a future oriented dimension. Notably, the availability of effective health-care requires the development of new medications for the treatment of formerly unattended diseases and health conditions. States have therefore a responsibility to foster pharmaceutical R&D to ensure that new medicines are made available.⁴⁹ In this consideration, particular regard shall be given to neglected tropical diseases that predominantly affect the poor in developing countries.⁵⁰

Moreover, in regard to the element of accessibility, the right to health requires that health-care facilities, programmes, goods and services are within safe physical reach of everyone, and provided without discrimination.⁵¹ The non-discrimination provision demands that special consideration is given to vulnerable and marginalised groups of the population, as elaborated below in 1.2.1.2.⁵² In addition to the physical accessibility of health-care, for the context of this thesis, especially economic accessibility, i.e. the affordability of health care goods and services is of crucial importance.⁵³ Economic accessibility requires, inter alia, that needed medications are affordable for everyone. This implies that states have a responsibility to take measures to prevent excessive pricing of pharmaceutical products, and to review import tariffs and tax policies which unreasonably interfere with the accessibility of medicines.⁵⁴

⁴⁶ *ibid* para 12(a).

⁴⁷ *ibid* para 12(a).

⁴⁸ Hunt P, Un Doc A/61/338 (n 41) para 47.

⁴⁹ *ibid* para 48.

⁵⁰ *ibid* para 47.

⁵¹ CESCR, *General Comment No. 14* (n 20) para 12(b).

⁵² *ibid* para 12(b).

⁵³ *ibid* para 12(b).

⁵⁴ Hunt P, Un Doc A/61/338 (n 41) para 49.

Again, special consideration shall be given to the poor, as their inability to afford expensive treatment methods makes them most vulnerable to economic discrimination.⁵⁵ It is now widely accepted that because of its vital importance for human health, the accessibility of medicines is an integral part of the right to health.⁵⁶

1.2.1.2 The Non-Discrimination Principle

According to the non-discrimination principle of human rights law, discrimination is prohibited with regard to all human rights.⁵⁷ In respect of economic, social, and cultural rights, such as the right to health, Article 2(2) and Article 3 ICESCR enumerate a list of grounds on which discrimination is prohibited.⁵⁸ Of special relevance for the scope of this thesis is the non-discrimination principle for reasons of social origin, social or other status, and property. In this regard, the CESCR reaffirms the special protection needs of people living in poverty even in situations of severe resource constraint of a member state to the ICESCR.⁵⁹ Consequently, it must be noted that the aim of the non-discrimination principle does not stipulate that everyone needs to be treated the same. Conversely, the differential treatment of marginalised groups of the population is not only justified, but rather required, as giving priority to people most in need is a precondition for the creation of a system of equal opportunity for everyone.⁶⁰

It is undeniable that there are major social and economic inequalities between different groups of peoples, so that considerations of justice and fairness appear to require that in some cases wealth is redistributed, and that vulnerable people are prioritised in order

⁵⁵ CESCR, *General Comment No. 14* (n 20) para 12(b).

⁵⁶ cf. Moon S, 'Respecting the Right to Access to Medicines: Implications of the UN Guiding Principles on Business and Human Rights for the Pharmaceutical Industry' (2013) 15 *Health and Human Rights* 32, 34.

⁵⁷ Clapham A, *Human Rights: A Very Short Introduction* (OUP 2007) 143.

⁵⁸ ICESCR (n 17) Articles 2(2) and 3.

Article 2(2) reads: The States Parties to the present Covenant undertake to guarantee that the rights enunciated in the present Covenant will be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

Article 3 reads: The States Parties to the present Covenant undertake to ensure the equal right of men and women to the enjoyment of all economic, social and cultural rights set forth in the present Covenant.

⁵⁹ CESCR, *General Comment No. 14* (n 20) para 18

⁶⁰ cf. Declaration of Alma-Ata (n 26) Article VII(6); Clapham A (n 57) 143.

to facilitate equality of outcomes.⁶¹ In this regard, the differential treatment of different classes of people, commonly considered as positive discrimination in human rights law, is based on the two fundamental principles of non-discrimination and equality.⁶² To achieve their goals, these principles must not be interpreted in a way that always demands equal treatment, as under certain circumstances states may rather be required to take specific measures for the benefit of disadvantaged groups.⁶³ This is especially relevant as certain groups, inter alia including lower-income groups, disproportionately suffer from violations of economic, social, and cultural rights.⁶⁴ In regard to the right to health, this is particularly true for the poor and under privileged, who commonly lack adequate or complete access to essential medicines.⁶⁵ States therefore have the obligation to provide the most vulnerable people with special means of accessing treatment, in order to ensure equality of access.⁶⁶

1.2.1.3 Progressive Realisation and International Assistance

As noted above, the ICESCR provides for the progressive realisation of the obligations of state parties, necessitating, however, that certain core obligations have to be performed immediately.⁶⁷ This distinction is important, as many developing countries lack adequate financial and material resources to implement all the required measures without delay, and because some human rights objectives require the creation of ongoing programmes to achieve the intended results over time.⁶⁸ Certain core obligations, on the other hand, are of such crucial importance for the protection of human integrity that their implementation has to be realised without any unreasonable delay.⁶⁹ A state's failure to perform those core obligations therefore amounts to a violation of economic, social, and cultural rights, even in situations of resource restrictions.⁷⁰ In consideration of the most vulnerable groups of people, the CESCR

⁶¹ Clapham A (n 57) 143-144.

⁶² Hunt P, Un Doc A/61/338 (n 41) para 53.

⁶³ *ibid* para 53.

⁶⁴ Maastricht Guidelines (n 42) Guideline 20.

⁶⁵ Khosla R and Hunt P (n 32) 5.

⁶⁶ CESCR, *General Comment No. 14* (n 20) para 19.

⁶⁷ *ibid* para 30; Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 3: The Nature of States Parties' Obligations* (Art. 2, Para. 1, of the Covenant) (14 December 1990) UN Doc E/1991/23, paras 2, 9, 10.

⁶⁸ CESCR, *General Comment No. 3* (n 67) paras 2, 9, 10.

⁶⁹ *ibid* para 2.

⁷⁰ *ibid* para 10; Maastricht Guidelines (n 42) Guidelines 9 and 10.

indicates that the core obligations under the right to health include, inter alia, that states ‘take measures to prevent, treat and control epidemic and endemic diseases’,⁷¹ and ‘ensure the right of access to health facilities, goods and services on a non-discriminatory basis’.⁷² Furthermore, while the accessibility of non-essential medicines is subject to the process of progressive realisation, the provision of essential medicines is of such vital necessity that it is an inevitable core obligation with immediate effect under the right to health.⁷³

Nevertheless, a considerable obstacle to the timely realisation of the right to health remains, as especially developing countries might not have the required resources readily available to guarantee the implementation of even their core obligations. This problem is recognised by the ICESCR, which therefore provides in Article 2(1) that the steps towards the realisation of the rights provided by the Covenant have to be taken both individually by states, as well as through international assistance and cooperation.⁷⁴ In accordance with the Declaration of Alma-Ata, the CESCR emphasises that the obligation of international assistance and cooperation is an obligation of all member states to the ICESCR.⁷⁵ The committee further indicates that wealthier states have responsibility to assist poorer countries where they can, and in a reasonable manner, especially by providing much needed resources, which can, inter alia, include the provision of monetary aid.⁷⁶ In this consideration, the CESCR suggests that the maximum of available resources entails both the resources in possession of individual states as well as the resources available through international assistance and cooperation.⁷⁷

Moreover, the international responsibilities of states towards the right to health go beyond the mere provision of donations to developing countries. In particular, international duties of all states can be derived from the obligations to respect and protect the right to health, which are not only applicable within a country’s territory, but in their relation to other countries as well.⁷⁸ State parties to the ICESCR have

⁷¹ CESCR, *General Comment No. 14* (n 20) para 44(c).

⁷² *ibid* para 43(a).

⁷³ *ibid* para 43(d); Hunt P, Un Doc A/61/338 (n 41) para 58.

⁷⁴ ICESCR (n 17) Article 2(1).

⁷⁵ CESCR, *General Comment No. 3* (n 67) para 14; Declaration of Alma-Ata (n 26) Article IX.

⁷⁶ CESCR, *General Comment No. 14* (n 20) para 40.

⁷⁷ CESCR, *General Comment No. 3* (n 67) para 13.

⁷⁸ CESCR, *General Comment No. 14* (n 20) para 39; Maastricht Guidelines (n 42) Guideline 18.

therefore an obligation to prevent non-state actors under their jurisdictional influence, such as the private business sector, from violating the right to health in other countries.⁷⁹ Furthermore, states shall pay due regard to the right to health, as well as other human rights, when entering into international agreements, ensuring that such agreements do not create obstacles for their realisation.⁸⁰ In this regard, and of particular importance for the scope of this thesis, it is submitted that wealthier states should particularly refrain from encouraging developing countries to adopt intellectual property standards which are designed to limit the safeguards and flexibilities provided by the TRIPS Agreement, as discussed in chapter 2.5.⁸¹ Furthermore, member states of international organisations are obliged to exercise their influence over these organisations to ensure that due regard is given to right to health considerations, safeguarding that no human rights violations emerge from international programmes and policies.⁸² Ultimately, a state entering into an international agreement which is likely to create obstacles for the enjoyment of the right to health, in either their own country or any other state, may amount to violation of the ICESCR.⁸³

1.2.2 Responsibilities of Non-State Actors

While it is undisputed that states are the main duty bearers of human rights obligations provided by international declarations and treaties, the CESCR clarifies that the realisation of the right to health further entails responsibilities of non-state actors, including civil-society and the private business sector.⁸⁴ In this context, states are encouraged to adopt measures for raising awareness of those responsibilities among non-state actors.⁸⁵ Regardless of the actual measures taken by states, there is growing consensus that society as a whole not only has ethical, but also certain legal responsibilities towards the realisation of international human rights law.⁸⁶ It is argued that such private responsibilities are logically consistent with the very teleological

⁷⁹ CESCR, *General Comment No. 14* (n 20) para 39.

⁸⁰ *ibid* para 39;

⁸¹ Hunt P, Un Doc A/61/338 (n 41) para 64.

⁸² CESCR, *General Comment No. 14* (n 20) para 39; Maastricht Guidelines (n 42) Guideline 19.

⁸³ CESCR, *General Comment No. 14* (n 20) para 50; Maastricht Guidelines (n 42) Guideline 15(i).

⁸⁴ CESCR, *General Comment No. 14* (n 20) para 42.

⁸⁵ *ibid* para 55.

⁸⁶ Khosla R and Hunt P (n 32) 3; Hunt P, 'Human Rights Guidelines for Pharmaceutical Companies' (n 33) Preamble para (h).

purpose of human rights law.⁸⁷ In this consideration, Wolff suggests that human rights ‘provide a statement of the minimum moral obligations owed to human beings simply by virtue of their existence as human beings’.⁸⁸ When considering that every right comes with a responsibility, it can be submitted that the minimum human rights responsibility of non-state actors is to respect, i.e. not to interfere with, the human rights of other groups or individuals. For a further discussion of the private actor responsibility to respect human rights, see chapter 5.1.3.1.

In context of the right to health, a UK Department for International Development policy paper clarifies that the ‘[r]esponsibility for increasing access to essential medicines rests with the whole international community.’⁸⁹ The policy paper further affirms that progress depends on everyone, which has to be regarded as including states as well as non-state actors.⁹⁰ Furthermore, the participation of non-state actors was particularly emphasised in Target 8.E of Millennium Development Goal (MDG) 8, aiming at the enhancement of access to affordable essential medicines in developing countries, to be achieved in cooperation with pharmaceutical companies.⁹¹ The involvement of the pharmaceutical industry in the strategy of the MDGs was of crucial relevance as several ministers and public officials still suggest that the implementation of the right to health is frequently obstructed by the policies and practices of certain pharmaceutical corporations.⁹² In this regard, high drug prices and a neglect of research into diseases that mainly affect the poor in developing countries have been defined as issues of particular concern.⁹³

⁸⁷ Khosla R and Hunt P (n 32) 3.

⁸⁸ Wolff J (n 21) 16.

⁸⁹ Department for International Development (DFID), ‘Increasing people’s access to essential medicines in developing countries: a framework for good practice in the pharmaceutical industry’ (March 2005) A UK Government Policy Paper
<<http://apps.who.int/medicinedocs/documents/s18384en/s18384en.pdf>> accessed 12 March 2019, 1.

⁹⁰ *ibid.*

⁹¹ United Nations, ‘Goal 8: Develop a Global Partnership for Development’
<<http://www.un.org/millenniumgoals/global.shtml>> accessed 20 May 2019; United Nations, ‘List of Millennium Development Goals, and Goal 8 Targets and Indicators’
<https://www.un.org/en/development/desa/policy/mdg_gap/mdg8_targets.pdf> accessed 20 May 2019.

⁹² Hunt P, ‘Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’ (11 August 2008) United Nations General Assembly, UN Doc A/63/263, para 23.

⁹³ *ibid* para 23.

In his role as UN Special Rapporteur on the right to health, Paul Hunt elaborated that while the CESCR confirms the general existence of the human rights responsibilities of the private business sector, those responsibilities are not further specified and therefore unclear.⁹⁴ It is therefore questionable, how non-state actors can be held to account when their obligations are not sufficiently defined.⁹⁵ Under his mandate, Hunt addressed this issue by developing the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines (the Guidelines), which aim to clarify what specific corporate right to health responsibilities should entail.⁹⁶ While the language used in the framework suggests a voluntary nature,⁹⁷ the Guidelines elaborate on what seems to be reasonably expected of pharmaceutical corporations. In this context, the Guidelines may be regarded as a suggestive interpretation of private human rights responsibilities which the CESCR left undefined.

In principle, Hunt proposes that the pharmaceutical industry has responsibilities towards enhancing the accessibility of medicines, as this is a core element of its societal mission.⁹⁸ In particular, corporations shall at least refrain from encouraging states to disregard their obligations arising from human rights law, including the right to health.⁹⁹ For the pharmaceutical industry, this is particularly relevant in consideration of its lobbying activity, by which corporations use their economic power to influence the actions taken by states.¹⁰⁰ Furthermore, corporations shall respect the right of states to make use of the flexibilities provided by the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health, to protect public health by enhancing the accessibility of patented medicines, as elaborated in chapter 2.3.¹⁰¹ For a further discussion of Hunt's Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, see chapter 5.1.3.2.

In summary, it can be reaffirmed that legal human rights responsibilities of non-state actors, including the private business sector, are currently not sufficiently defined and therefore unclear. That non-state actor responsibilities towards the right to health

⁹⁴ *ibid* para 26.

⁹⁵ *ibid* para 27.

⁹⁶ Hunt P, 'Human Rights Guidelines for Pharmaceutical Companies' (n 33).

⁹⁷ Hunt P, UN Doc A/63/263 (n 92) para 46.

⁹⁸ Hunt P, 'Human Rights Guidelines for Pharmaceutical Companies' (n 33) Preamble paras (i) and (l).

⁹⁹ *ibid* Guideline 4.

¹⁰⁰ *ibid* Guideline 26.

¹⁰¹ *ibid* Guideline 27.

nevertheless exist, can be submitted when accepting that every right comes with a responsibility, as suggested by Article 29(1) UDHR which provides that '[e]veryone has duties to the community'.¹⁰² In this consideration, this thesis aims to contribute to the debate on corporate human rights responsibilities with a particular focus on the responsibilities of pharmaceutical patent holders towards the realisation of the right to health.

1.3 The Indispensability of Health for the realisation of other Human Rights

Both the Vienna Declaration and Programme of Action and the Maastricht Guidelines on Violations of Economic, Social and Cultural Rights unambiguously determine that by nature all human rights are indivisible, interdependent, and interrelated, and thus cannot be regarded in isolation from each other.¹⁰³ In this regard, the CESCR defines health as 'a fundamental human right indispensable for the exercise of other human rights.'¹⁰⁴ To put it differently, violations of the right to health, or its insufficient realisation, may result in direct impairments to the realisation of other human rights, including, but not limited to the rights to education, to work, to development, and to life.¹⁰⁵

None of these rights can be fully realised without the enjoyment of the right to health, as health conditions directly impact on the capability of individuals and groups to achieve an adequate standard of living.¹⁰⁶ A first thing to remember is that good health is a prerequisite for the capability of human beings to engage in a meaningful life by learning through education and by engaging in work to earn an income, and assure a livelihood.¹⁰⁷ Education and work are thus indispensable for the realisation of the right to development, as they are an integral precondition for escaping poverty, and thereby

¹⁰² UDHR (n 1) Article 29(1).

¹⁰³ *Vienna Declaration and Programme of Action* (n 9), para 5; Maastricht Guidelines (n 42) Guideline 4.

¹⁰⁴ CESCR, *General Comment No. 14* (n 20) para 1.

¹⁰⁵ *ibid* para 3; UN Office of the High Commissioner for Human Rights (OHCHR), 'Fact Sheet No. 31: The Right to Health' (June 2008)

<<https://www.ohchr.org/Documents/Publications/Factsheet31.pdf>> accessed 13 February 2019, 6.

¹⁰⁶ cf. OHCHR, 'Fact Sheet No. 31' (n 105) 6.

¹⁰⁷ *Ibid*.

for achieving both the development of groups and individuals, as well as of developing countries as a whole.

Of paramount importance for the most basic of human needs, however, is the interrelationship between the right to health and the supremely fundamental human right to life itself. The right to life was first adopted by Article 3 UDHR which simply provides that '[e]veryone has the right to life'.¹⁰⁸ This right was then reaffirmed by the International Covenant on Civil and Political Rights (ICCPR) in 1966 which provides in Article 6(1):

Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.¹⁰⁹

In 2018, the Human Rights Committee adopted General Comment No.36 on Article 6 of the International Covenant on Civil and Political Rights, on the right to life, providing in paragraph 2 that the right to life 'is the supreme right from which no derogation is permitted', that the right 'is most precious for its own sake as a right that inheres in every human being', and that its 'protection is the prerequisite for the enjoyment of all other human rights'.¹¹⁰ While it is commonly defined as a civil and political right, the right to life both impacts and is impacted by economic and social rights as well. In particular, the realisation of the right to health has direct effects on the realisation of the right to life, and the provision of life-saving health care under the right to health saves human lives. In this consideration, General Comment No.36 indicates that states have a duty to address societal conditions threatening the enjoyment of the right to life, including prevalent life-threatening diseases.¹¹¹ In particular, the Human Rights Committee provides that states shall adopt measures to ensure the access to essential health care without delay.¹¹² It follows that the accessibility of life-saving medicines is a human rights requirement under both the right to health as well as the right to life. In further consideration of their importance

¹⁰⁸ UDHR (n 1) Article 3.

¹⁰⁹ International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) [ICCPR], Article 6.

¹¹⁰ Human Rights Committee, *General Comment No. 36 on Article 6 of the International Covenant on Civil and Political Rights, on the Right to Life* (30 October 2018) UN Doc CCPR/C/GC/3, para 2.

¹¹¹ *ibid* para 26.

¹¹² *ibid*.

for a human life in dignity,¹¹³ it can be submitted that the realisation and protection of both the right to health and the right to life lies at the very core of all human and other rights.

1.4 Concluding Remarks

This chapter has demonstrated that the right to health is a fundamental right in that its enjoyment constitutes a necessary precondition for the realisation of other human rights. In this regard, it is noted that the right to health is applicable to everyone without discrimination, and that special measures are therefore required for the protection of marginalised groups and people living in poverty. Due to its adoption in a number of international human rights treaties, the right to health is of legally binding effect, imposing direct obligations on states. In general, these human rights obligations can be divided into three categories, namely obligations to respect, to protect and to fulfil. Summarised, states then have negative obligations preventing them from unduly interfering with the enjoyment of the right to health, as well as positive obligations requiring the adoption of measures towards the realisation and protection of the right to health, including measures regulating the activities of non-state actors. Notably, the obligations of states are not constrained by national boundaries as states have a duty to provide international assistance to facilitate the realisation of the right to health in lower-income countries. Furthermore, states shall refrain from the adoption of international agreements that are likely to create obstacles for the enjoyment of the right to health both nationally and/or in other countries.

¹¹³ *ibid* para 26; CESCR, *General Comment No. 14* (n 20) 1; Maastricht Guidelines (n 42) Guideline 4.

For the purpose of this thesis, the reference to the term ‘life in dignity’ acknowledges the inherent value of all human beings, simply based on their existence. This acknowledgment of the value of human life exceeds the simple concept of physical or biological life, and rather entails a specific respect for the uniqueness and irreplaceability of individual human existence, and the necessary conditions to make each life worth living. While it is recognised here that these conditions entail subjective, cultural, and moral elements, and may thus be perceived differently by different groups of people, the author suggests that a certain core value can be attributed to the concept of a dignified life, which I regard as the freedom from unnecessary or preventable suffering. In the context of this thesis, the achievement of a life in dignity is therefore to be seen in the realisation of living conditions that enable individuals to engage in a meaningful life, without obstacles that expose them to preventable suffering, such as the inaccessibility of medicines for treatable conditions. For a further discussion of the broader concept of human dignity, the necessary conditions to achieve a dignified life, and their connection to the concept of human agency, see chapter 3.2.1.2.

While states are commonly regarded as the main duty bearers under international human rights law, it is now widely accepted that the right to health implies responsibilities for non-state actors as well. As these responsibilities, however, are currently not sufficiently defined by international human rights law, and therefore unclear, this thesis contributes to debates on the human rights responsibilities of private corporations, with a particular focus on the patent holding pharmaceutical industry.

Lastly, in consideration of the teleological purpose behind the right to health, it can be observed that the accessibility and the affordability of medicines are integral requirements of the right to health, as the highest attainable standard of health is only attainable when all people have access to affordable medical treatment. Of similar importance, is that medicines are available in the first place. As elaborated in sub-chapter 1.2.1.1, the availability requirement extends to the availability of new medicines in the future, so that states have an obligation to promote effective pharmaceutical research. It follows that states have an obligation to realise both the accessibility of medicines now as well as the availability of new drugs in the future. To ensure that both the accessibility and the availability requirements are appropriately fulfilled, it is submitted that states have a duty to ensure that the promotion of pharmaceutical research does not create obstacles for the accessibility of the fruits of such research activities. This is of particular relevance in respect of patent rights, which are currently the main research incentive provided to pharmaceutical corporations, as elaborated in the next chapter.

Chapter Two

2 The International Patent Regime

To understand how pharmaceutical patent rights impact on the realisation of the right to health in developing countries and least-developed countries (LDCs), chapter 2 provides an overview of the current international patent regime, elaborating on the scope of patent rights as regulated under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and so-called TRIPS-Plus trade agreements. In particular, this chapter aims to explain the general functioning of international patent standards, outlining the potentially harmful consequences, inherent to the granting of imbalanced exclusive private rights. To this end, sub-chapter 2.1 briefly introduces the evolution of the international intellectual property (IP) and patent regime, to indicate the distinct power imbalances between industrialised and developing countries in the negotiations that ultimately led to the adoption of the TRIPS Agreement. Successively, sub-chapters 2.2 and 2.3 provide a brief overview of the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) respectively. Sub-chapter 2.4 then addresses the interpretation of the provisions of the TRIPS Agreement in light of the Doha Declaration, with a particular focus on patent standards and other interrelated regulations relevant for understanding the impacts of pharmaceutical patents on the accessibility of medicines and public health. Lastly, sub-chapter 2.5 elaborates on TRIPS-Plus trade agreements, which are international agreements that implement higher IP and patent protection standards than those required by TRIPS, further aggravating the detrimental impacts of pharmaceutical patent rights on public health in developing countries.

2.1 The Evolution of the International IP and Patent Regime

Initially, the protection of IP, and particularly of patents, was introduced by national laws, seeking to benefit society by encouraging the development of new technologies, or the importation of technologies from abroad, into a country's domain.¹ In the 18th and 19th century, the growing importance of international trade then led to the recognition that a cross-border IP and patent protection creates mutual benefits for the countries involved, protecting their inventions from replication in other countries.² In 1883, the first multinational treaty in the area of IP protection, namely the Paris Convention for the Protection of Industrial Property, was concluded among eleven states³ and regulated the treatment of patents, trademarks, industrial designs, utility models, service marks, trade names, and the repression of unfair competition between the signatory countries.⁴ While the Paris Convention does not define the substantive elements of patent laws, other than providing that patents shall be protected, it includes various reforms, regulating how patents shall be treated in a multinational context.⁵ The Paris Convention, however, leaves governments free to self-determine what is patentable and what is not, in that Article 1(4) defines that patents shall include all forms of industrial patents which are recognised by a country's national laws.⁶ The basic principle of the convention, to be found in Article 2, then provides for the

¹ cf. Brinkhof J, 'On Patents and Human Rights' in Grosheide W (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar Publishing 2010) 143; Shiva V, *Protect or Plunder? Understanding Intellectual Property Rights* (ZED Books 2001) 14; Waelde C and others, *Contemporary Intellectual Property: Law and Policy* (4th edn, OUP 2016) para 10.4.

² Gervais DJ, 'The Internationalization of Intellectual Property: New Challenges from the Very Old and the Very New' (2002) 12 *Fordham Intellectual Property, Media and Entertainment Law Journal* 929, 935; Waelde C and others (n 1) para 10.12.

³ The initial signatory countries consisted of Belgium, Brazil, France, Guatemala, Italy, the Netherlands, Portugal, El Salvador, Serbia, Spain and Switzerland. See thereto: WIPO, 'Contracting Parties: Paris Convention' <https://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2> accessed 27 April 2019; WIPO, 'Contracting Parties: Paris Convention: Guatemala' <https://www.wipo.int/treaties/en/remarks.jsp?cnty_id=237C> accessed 27 April 2019; WIPO, 'Contracting Parties: Paris Convention: Serbia' <https://www.wipo.int/treaties/en/remarks.jsp?cnty_id=1383C> accessed 27 April 2019; WIPO, 'Contracting Parties: Paris Convention: El Salvador' <https://www.wipo.int/treaties/en/remarks.jsp?cnty_id=225C> accessed 27 April 2019.

⁴ WIPO, 'Summary of the Paris Convention for the Protection of Industrial Property (1883)' <https://www.wipo.int/treaties/en/ip/paris/summary_paris.html> accessed 27 April 2019.

⁵ Waelde C and others (n 1) para 10.12.

⁶ Paris Convention for the Protection of Industrial Property (signed 20 March 1883, entered into force 7 July 1884, last amended 28 September 1979) [Paris Convention], Article 1(4).

national treatment of the citizens of all signatory countries.⁷ This means that nationals of all parties to the Paris Convention shall enjoy the same treatment and protection as the citizens of the country where a patent is issued.⁸

Three years after the adoption of the Paris Convention, the Berne Convention for the Protection of Literary and Artistic Works of 1886 was concluded, becoming the second multinational IP agreement, regulating cross-border protection in the field of copyrights.⁹ Revised versions of the Paris and Berne Conventions still remain at the core of the international IP system today, with their territorial applicability substantially extended by the TRIPS Agreement, mandating all WTO members to adhere to the basic elements of these conventions.¹⁰ Initially, specialised secretariats were established for each of the conventions, which, in 1893, were combined to form the *Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle*¹¹ (BIRPI), which had the main purpose of administering the two Conventions.¹² Signed in 1967, and coming into force in 1970, the Convention establishing the World Intellectual Property Organisation (WIPO), then transformed the BIRPI into the still operating WIPO,¹³ with the purpose of promoting ‘the protection of intellectual property throughout the world’.¹⁴ In 1974 the WIPO joined the United Nations, becoming a member of the UN Specialized Agencies.¹⁵ While mainly continuing the administration of international IP treaties, the WIPO further serves as a forum for negotiations on international IP rights.¹⁶ Under the auspices of the WIPO, a number of

⁷ *ibid* Article 2.

⁸ Abbott FM, ‘Intellectual Property Rights in World Trade’ in Guzman AT and Sykes AO (eds), *Research Handbook in International Economic Law* (Edward Elgar Publishing 2007) 451

⁹ cf. WIPO, ‘Summary of the Berne Convention for the Protection of Literary and Artistic Works (1886)’ <https://www.wipo.int/treaties/en/ip/berne/summary_berne.html> accessed 27 April 2019.

¹⁰ Hughes J, ‘A Short History of Intellectual Property in Relation to Copyright’ (2012) 33 *Cardozo L. Rev.* 1293, 1299; Waelde C and others (n 1) para 10.13.

¹¹ French for ‘United International Bureaux for the Protection of Intellectual Property’.

¹² Hughes J (n 10) 1299; WIPO, ‘WIPO – A Brief History’ <<https://www.wipo.int/about-wipo/en/history.html>> accessed 27 April 2019.

¹³ WIPO, ‘Convention Establishing the World Intellectual Property Organization’ <<https://www.wipo.int/treaties/en/convention/>> accessed 27 April 2019.

¹⁴ Convention Establishing the World Intellectual Property Organization (adopted 14 July 1967, entered into force 26 April 1970, last amended 28 September 1979) [WIPO Convention], Article 3.

¹⁵ WIPO, ‘WIPO – A Brief History’ (n 12).

¹⁶ Abbott FM, ‘Intellectual Property Rights in World Trade’ (n 8) 475.

IP treaties were concluded, including the Patent Cooperation Treaty (PCT) of 1970, which established an international filing system for patent applications.¹⁷

Towards the end of the 1970s, industries in the global North increasingly recognised the correlation between IP protection and profitability in international trade, expressing particular concerns about what they considered insufficient IP protection standards in developing countries.¹⁸ Consequently, by the mid-1980s, the WIPO faced a decisive conflict of interests amongst its members, with industrialised countries demanding higher levels of IP protection, while the developing world, seeking for improved ways of transferring technologies from the North to the South, demanded more flexibility.¹⁹ As negotiations at WIPO level failed, and industrialised nations began to realise that stronger IP protection was difficult, if not impossible to achieve within the WIPO IP regime, the United States, Japan, and European Communities shifted their attention to the General Agreement on Tariffs and Trade (GATT).²⁰ It was particularly favourable for industrialised countries to introduce the debates on international IP protection to the GATT, where they had considerably greater influence than at WIPO level, as developing countries strongly relied on the GATT to facilitate exports of their products to the global North.²¹

Substantive negotiations on international IP laws began in the early 1990s, when industrialised nations introduced first draft texts to the Uruguay Round of GATT negotiations.²² The aim of the Uruguay Round was to facilitate increased international trade, which would then enhance the economic situation of developing countries.²³ The negotiations of IP rights, however, were strongly opposed by developing countries – led by Argentina, Brazil and India – which considered stringent IP protection at GATT level as a threat to their economic development progress.²⁴ While thus not convinced that the benefits of increased trade would eventually outweigh the negative

¹⁷ The Patent Cooperation Treaty (signed 19 June 1970, entered into force 24 January 1978, last modified 3 October 2001); WIPO, 'PCT – The International Patent System' <<https://www.wipo.int/pct/en/>> accessed 27 April 2019; WIPO, 'WIPO – A Brief History' (n 12). While the PCT constitutes an important development in the field of international patent protection, this filing system is of no further relevance to this thesis, which predominantly focusses on the international patent protection standards under the TRIPS patent regime.

¹⁸ Abbott FM, 'Intellectual Property Rights in World Trade' (n 8) 452.

¹⁹ *ibid* 452-453.

²⁰ *ibid* 453.

²¹ *ibid*.

²² Gervais DJ, 'The Internationalization of Intellectual Property' (n 2) 945.

²³ *cf.* Waelde C and others (n 1) para 10.43.

²⁴ Abbott FM, 'Intellectual Property Rights in World Trade' (n 8) 453.

impacts of stronger IP protection, developing countries ultimately succumbed to power imbalances and economic pressure, and reluctantly accepted the proposed IP provisions.²⁵ As a result, the Uruguay Round culminated in the establishment of the World Trade Organization (WTO) in 1995,²⁶ and the harmonisation of international IP laws, regulated by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).²⁷

2.2 The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

Adopted, and signed in Marrakech in 1994, and coming into force on 1 January 1995, the TRIPS Agreement aims at harmonising international IP laws, and constitutes the first international treaty regulating the substantive patent laws of all signatory states.²⁸ Being considered the most comprehensive international agreement on IP law,²⁹ global requirements for IP protection are set for all members of the WTO, which currently is comprised of 164³⁰ countries at all levels of economic development.³¹ The TRIPS Agreement provided a one-year transitional period, until 1 January 1996, from which date and thereafter all developed WTO member states had to comply with the provisions set forth in the agreement.³² Additionally, the TRIPS Agreement was, and is, subject to further transitional periods, for developing and least-developed country (LDC) members, taking account of their special needs and requirements, as elaborated below in 2.4.5.³³

²⁵ *ibid.*

²⁶ WTO, 'The WTO' <https://www.wto.org/english/thewto_e/thewto_e.htm> accessed 26 May 2019.

²⁷ Abbott FM, 'Intellectual Property Rights in World Trade' (n 8) 453.

²⁸ See thereto: GRAIN, 'One global patent system? WIPO's Substantive Patent Law Treaty' <<https://www.grain.org/en/article/109-one-global-patent-system-wipo-s-substantive-patent-law-treaty>> accessed 28 April 2019; WTO, 'Overview: the TRIPS Agreement' <https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> accessed 28 April 2019.

²⁹ Pires de Carvalho N, *The TRIPS Regime of Patent Rights* (2nd edn, Kluwer Law International 2005) 28.

³⁰ WTO, 'Members and Observers' <https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm> accessed 26 May 2019.

³¹ Ho CM, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 56-57.

³² Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (signed 15 April 1994, entered into force 1 January 1995) [TRIPS Agreement], Article 65(1).

³³ *ibid* Articles 65 and 66.

Article 2 TRIPS establishes that the TRIPS Agreement shall not interfere with obligations WTO members may have towards each other under prior existing IP conventions, including the Paris Convention and the Berne Convention, and further extends the applicability of parts of the Paris Convention to all WTO members.³⁴ Similar to the Paris Convention, the WTO legal system builds upon a non-discrimination principle, prohibiting measures taken by a WTO member that discriminate against nationals of other WTO member states.³⁵ The national treatment principle found in Article 3 TRIPS, for example, was already established in both the Paris and the Berne Conventions, and requires that WTO members treat nationals of other WTO members at least as favourable as they treat their own nationals with regard to IP protection.³⁶ The wording of Article 3 TRIPS – ‘no less favourable than that it accords to its own nationals’ – suggests that TRIPS provides a flexibility to treat foreign nationals more favourable than domestic citizens. The TRIPS negotiators therefore recognised the possibility that, as a result of power imbalances in bilateral agreements, some countries may be willing to grant higher levels of IP protection to nationals of another country than to its own citizens.³⁷ In this consideration, Article 4 TRIPS introduced the Most-Favoured-Nation (MFN) treatment, mandating that any advantages granted by one WTO member to nationals of any other WTO member shall ‘immediately and unconditionally’ be accorded to the nationals of all WTO members.³⁸

The main advancement towards the harmonisation of international IP laws, established by the TRIPS Agreement, can be seen in the requirement that all WTO member states at least implement the minimum IP protection levels defined in the agreement, as elaborated below in 2.4.2.1.³⁹ Furthermore, the TRIPS Agreement shifted the scope of international IP protection from soft law to hard law.⁴⁰ Not only are WTO member states required to implement enforcement mechanisms for infringements of IP rights

³⁴ *ibid* Article 2.

³⁵ Ho CM (n 31) 57; Sellin J, *Access to Medicines: The Interface between Patents and Human Rights. Does one size fit all?* (Intersentia 2014) 163; UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 89.

³⁶ Sellin J (n 35) 163; UNCTAD-ICTSD (n 35) 62.

³⁷ UNCTAD-ICTSD (n 35) 63.

³⁸ TRIPS Agreement (n 32) Article 4.

³⁹ *ibid* Article 1(1).

⁴⁰ Lucyk S, ‘Patents, Politics and Public Health: Access to Essential Medicines Under the TRIPS Agreement’ (2007) 38 *Ottawa Law Review* 191, 195.

into national law,⁴¹ but further, the IP protection introduced by the TRIPS Agreement is linked to the WTO dispute settlement system. Under this Dispute Settlement Understanding (DSU), which is compulsory and binding, WTO member states can submit complaints against other WTO members for implementing TRIPS-inconsistent measures into their national laws.⁴²

It must be noted here that the provision of IP rights under WTO law is not to be seen as a self-contained means for the sole purpose of protecting the interests of rights holders. In its objectives and principles, as analysed below in 2.4.2.3, the TRIPS Agreement rather defines that IP rights shall constitute a means to an end, serving a broader public interest. In particular, TRIPS shall reduce distortions and impediments to international trade, by promoting *adequate* protection, while ensuring that IP rights do not themselves become barriers to legitimate trade.⁴³ While this shall promote ‘technological innovation and the transfer and dissemination of technology,’ a balance of rights and obligations shall ensure the compliance with social and economic welfare.⁴⁴ In this regard, and pertinent to the focus of this thesis, Article 8 TRIPS explicitly recognises the right of WTO members to adopt measures to protect public health and nutrition, and to prevent the abuse of IP rights, as long as such measures are consistent with the provisions of the agreement.⁴⁵

Of particular relevance for the purpose of this thesis, are the provisions regulating the protection of patents found in Section 5 of Part II of the TRIPS Agreement, and the protection of undisclosed information found in Section 7 of Part II. As analysed below in 2.4.3, Articles 27 to 34 TRIPS provide standards concerning the scope and applicability of patent rights, mandating the availability of patents for products and processes in all fields of technology, including pharmaceutical products, provided that they are new, involve an inventive step, and are capable of industrial application.⁴⁶ Patents under TRIPS provide their owners with exclusive rights⁴⁷ for a minimum patent term of 20 years from the date of filing a patent application.⁴⁸ The exclusive

⁴¹ TRIPS Agreement (n 32) Article 41.

⁴² Lucyk S (n 40) 195.

⁴³ TRIPS Agreement (n 32) Preamble para 1.

⁴⁴ *ibid* Article 7.

⁴⁵ *ibid* Article 8.

⁴⁶ *ibid* Article 27(1).

⁴⁷ *cf.* *ibid* Article 28.

⁴⁸ *ibid* Article 33.

rights conferred by Article 28 TRIPS are subject, however, to exceptions provided for in Articles 30 and 31 TRIPS, establishing limitations and flexibilities for the protection of public interests.⁴⁹ As further elaborated below in 2.4.3.6 and 2.4.3.7, these exceptions are commonly regarded as not being sufficiently equipped to adequately alleviate the negative consequences of pharmaceutical patent rights.⁵⁰ Additionally, Article 39 TRIPS further strengthens the private rights of pharmaceutical IP owners by mandating the protection of undisclosed information, including data submitted as a condition for the marketing approval of pharmaceutical products.⁵¹

From its outset, the TRIPS Agreement was criticised for not adequately taking into account the problems and special needs of developing countries.⁵² As outlined in the introduction to this thesis, it is commonly accepted that by restricting generic competition, the exclusive rights granted by pharmaceutical patents can significantly impinge upon the pricing of medical products.⁵³ Further, considering that the prices of pharmaceutical products directly determine their accessibility, it can be observed that, particularly in developing countries with high levels of poverty, even marginal increases of medicine prices can have severe impacts on the realisation of public health.⁵⁴ In this regard, it can be argued that the TRIPS Agreement established an imbalanced patent regime favouring the interests of patent holders, without paying due regard to the public interests of developing countries.⁵⁵

⁴⁹ *ibid* Articles 30 and 31.

⁵⁰ *cf.* Lucyk S (n 40) 193.

⁵¹ TRIPS Agreement (n 32) Article 39.

⁵² As elaborated below in 2.4.5, the TRIPS Agreement provided transitional periods for developing countries and LDCs, explicitly taking account of their specific needs. These transitional periods, however, only delayed the problems, but did not mitigate the issues expected to arise from the specific IP provisions of the TRIPS Agreement, once the transitional periods expired.

⁵³ Forman L, 'From TRIPS-Plus to Rights Plus? Exploring Right to Health Impact Assessment of Trade-Related Intellectual Property Rights through the Thai Experience' (2012) 7 AJWH 347, 351; Forman L, 'Trade Rules, Intellectual Property, and the Right to Health' (2007) 21 Ethics & International Affairs 337, 339.

⁵⁴ Hestermeyer H, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (OUP 2007) 78; Hunt P and others, *Neglected Diseases: A Human Rights Analysis* (WHO 2007) 33; Forman L, 'From TRIPS-Plus to Rights Plus?' (n 53) 350; Sellin J (n 35) 23.

⁵⁵ Lucyk S (n 40) 196.

2.3 The Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration)

In the light of the extensive exclusive rights granted to patent owners, the mandatory introduction of patents for pharmaceutical products under TRIPS raised severe concerns among developing countries about the impacts pharmaceutical patents will have on public health and access to medicines.⁵⁶ In particular with regard to the worsening of the HIV/AIDS pandemic around the turn of the century, Zimbabwe, on behalf of the African Group and supported by other developing countries, requested a special session of the TRIPS Council to address those concerns.⁵⁷ The papers submitted to this session by developing country groups elaborated on the specific problems arising from the provisions of TRIPS, including concerns about how industrialised countries invoked claims on behalf of their industry groups.⁵⁸

Examples of those concerns can be seen in the way the US and the EU, on behalf of their research-based pharmaceutical industries, campaigned against developing countries that intended to make use of the flexibilities provided by TRIPS, such as South Africa in the early 2000s.⁵⁹ At that time, South Africa was about to introduce health reform legislation in order to deal with the acute HIV/AIDS pandemic, which was opposed by several developed country groups and pharmaceutical corporations that invoked litigation and threatened trade and economic sanctions.⁶⁰ It was only the work of NGOs, and an immense public outcry that eventually led to the withdrawal of these claims.⁶¹ Similarly, the US initiated dispute settlement proceedings under the WTO DSU against Brazil, which was widely perceived as directed against Brazil's successful HIV/AIDS treatment program that relied upon the use of compulsory licenses to provide affordable generic antiretrovirals (ARVs).⁶² While the US eventually withdrew its complaint, these cases highlighted the concerns of developing

⁵⁶ cf. Abbott FM, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) 5 JIEL 469, 480; Forman L, 'From TRIPS-Plus to Rights Plus?' (n 53) 351; Forman L, 'Trade Rules' (n 53) 339.

⁵⁷ Abbott FM, 'The Doha Declaration on the TRIPS Agreement and Public Health' (n 56) 481; Correa CM, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (WHO 2002) 1; Lucyk S (n 40) 197.

⁵⁸ Abbott FM, 'The Doha Declaration on the TRIPS Agreement and Public Health' (n 56) 481-482.

⁵⁹ *ibid* 471.

⁶⁰ *ibid*.

⁶¹ *ibid*.

⁶² cf. *ibid*.

countries that the TRIPS Agreement could be utilised in a way that jeopardised the realisation of public health.⁶³

The concerns of developing countries were addressed at the Fourth WTO Ministerial Conference from 9 to 14 November 2001 which adopted the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) on 14 November 2001.⁶⁴ While the exact legal status of the Doha Declaration is unclear, it represents a strong political statement in the form of a Ministerial decision, and could be further considered a subsequent agreement, as defined in Article 31 paragraph 3(a) of the Vienna Convention on the Law of Treaties.⁶⁵ In this respect, it seems generally accepted that the Doha Declaration constitutes an authoritative interpretation of the TRIPS Agreement, which developing members can rely upon when implementing domestic IP provisions.⁶⁶

Paragraph 1 of the Doha Declaration recognises the gravity of public health problems faced by many developing countries. While this provision specifically refers to HIV/AIDS, tuberculosis and malaria, it further explicitly mentions other epidemics, indicating that the Declaration is not limited to certain diseases.⁶⁷ Paragraph 2 then stresses the need for the TRIPS Agreement to ‘be part of the wider national and international action to address these problems.’⁶⁸ This indicates that while the TRIPS Agreement can be part of the problem, depending on national implementation, it could also be used as a means to address such public health needs.⁶⁹ In this consideration, paragraph 3 of the Doha Declaration recognises the importance of IP protection for the development of new medicines, while also recognising the potential negative effects

⁶³ *ibid* 471-472.

⁶⁴ World Trade Organization (WTO), ‘Doha Declaration on the TRIPS Agreement and Public Health: Ministerial Declaration of 14 November 2001’ (20 November 2001) WTO Doc WT/MIN(01)/DEC/2 [Doha Declaration]; Lucyk S (n 40) 197.

⁶⁵ Correa CM, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (n 57) 11-12 and 44; Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) [VCLT], Article 31(3)(a).

⁶⁶ *cf.* Lucyk S (n 40) 198-199; Correa CM, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (n 57) 44-45; Abbott FM, ‘The Doha Declaration on the TRIPS Agreement and Public Health’ (n 56) 489.

⁶⁷ Doha Declaration (n 64) Paragraph 1.

⁶⁸ *ibid.* Paragraph 2.

⁶⁹ Correa CM, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (n 57) 7.

on the pricing of medicines.⁷⁰ In consideration of paragraphs 1 to 3, paragraph 4 of the Doha Declaration provides:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.⁷¹

There are different ways to interpret this provision. On the one hand, it is possible to regard paragraph 4 as 'a statement of fact', simply reaffirming that within the TRIPS flexibilities public health overrides commercial interests, without rebalancing the TRIPS Agreement.⁷² On the other hand, it can be suggested that when IP rights may be in conflict with public health objectives, IP rights under TRIPS should not create obstacles for public health.⁷³ Either way, the adoption of the Doha Declaration explicitly acknowledged public health as a purpose of the TRIPS Agreement, reaffirming that IP provisions can be interpreted and implemented in ways which are conducive to public health objectives.⁷⁴

Paragraph 5 of the Doha Declaration has important political and legal implications, in that it provides a non-exhaustive interpretation of the largely undefined flexibilities provided for by the TRIPS Agreement with particular respect to public health.⁷⁵ In essence, paragraph 5(a) reaffirms the importance of the objectives and purposes of Articles 7 and 8 TRIPS for the interpretation of the substantial IP provisions of the agreement.⁷⁶ Furthermore, paragraph 5(b) explicitly acknowledges compulsory licensing as a legitimate flexibility provided for by Article 31 TRIPS, and reaffirms the freedom of member states 'to determine the grounds upon which such licenses are granted'.⁷⁷ Paragraph 5(c) of the Doha Declaration then reaffirms the undisputed right of every sovereign nation to self-determine national emergencies and other

⁷⁰ Doha Declaration (n 64) Paragraph 3.

⁷¹ *ibid* Paragraph 4.

⁷² Correa CM, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (n 57) 11.

⁷³ *ibid* 11.

⁷⁴ *ibid* 11-12.

⁷⁵ *ibid* 13.

⁷⁶ Doha Declaration (n 64) Paragraph 5(a); cf. Correa CM, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (n 57) 14.

⁷⁷ Doha Declaration (n 64) Paragraph 5(b); cf. Correa CM, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (n 57) 15.

circumstances of extreme urgency, which is of particular importance for the applicability of certain exceptions to patent rights, as further elaborated below in 2.4.3.7.⁷⁸ Lastly, paragraph 5(d) reaffirms the right of member states to establish their own regime of exhaustion of IP rights, without challenge, the significance of which is addressed below in 2.4.2.2.⁷⁹ While paragraph 5 of the Doha Declaration does not amend the substantive scope of the TRIPS Agreement, the reaffirmation of the agreement's flexibilities is of considerable importance for clarifying their interpretation.⁸⁰ Notably, prior to the adoption of the Doha Declaration, many developing countries refrained from utilising these flexibilities in their domestic implementation of the TRIPS Agreement, because of their unclear wording.⁸¹

Paragraph 6 of the Doha Declaration then addresses specific issues arising from Article 31(f) TRIPS, as discussed in detail below in 2.4.3.7 and 2.4.3.8, which mandates that compulsory licenses shall be granted predominately for the supply of the domestic market.⁸² In this regard, paragraph 6 recognises that 'WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.'⁸³ This recognition was of major importance, as when the Doha Declaration was concluded developing countries were not yet required to provide patent protection for pharmaceuticals.⁸⁴ At that time, developing countries with pharmaceutical manufacturing capacities, such as India, provided cheaper generic medicines to other developing countries and LDCs in need of such medications.⁸⁵ With the end of the transitional periods for developing countries in 2005, as elaborated below in 2.4.5, this situation, however, would change, and developing countries could no longer supply generic copies of patented drugs.⁸⁶ For developing countries and LDCs without sufficient manufacturing capacities, the compulsory licensing exception was then

⁷⁸ Doha Declaration (n 64) Paragraph 5(c); cf. Correa CM, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (n 57) 16.

⁷⁹ Doha Declaration (n 64) Paragraph 5(d).

⁸⁰ Correa CM, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (n 57) 18.

⁸¹ *ibid* 18.

⁸² TRIPS Agreement (n 32) Article 31(f).

⁸³ Doha Declaration (n 64) Paragraph 6.

⁸⁴ Correa CM, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (n 57) 20.

⁸⁵ *ibid*.

⁸⁶ cf. *ibid*.

useless, as they could neither produce their own generic drugs, nor import cheaper generic medicines under such a license.

In response to this concern, the Doha Declaration instructed the Council for TRIPS to find an expeditious solution to this problem,⁸⁷ which culminated in the *WTO General Council's Decision on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health* on 30 August 2003, providing eligible members⁸⁸ with a waiver of Articles 31(f) and 31(h) TRIPS for pharmaceutical products.⁸⁹ In accordance with those waivers, countries with manufacturing capacity can now utilise compulsory licenses to export generic pharmaceuticals to countries without sufficient manufacturing capacities.⁹⁰ On 6 December 2005, the WTO General Council decided to permanently implement this interim waiver, by amendment, into the TRIPS Agreement, subject to the acceptance by two-thirds of WTO member states, as required by Article X(3) of the WTO Agreement.⁹¹ While WTO members initially had until 1 December 2007 to accept the amendment,⁹² the two-thirds majority was only reached in 2017. On 23 January 2017, the amendment of the TRIPS Agreement entered into force, introducing Article 31*bis*, and an Annex to the TRIPS Agreement, as further discussed below in 2.4.3.8.⁹³

Lastly, paragraph 7 of the Doha Declaration reaffirms the commitment to encourage and promote technology transfer to LDCs.⁹⁴ More importantly, however, the second sentence of paragraph 7 provided a waiver for LDCs, effectively extending the transitional period for pharmaceutical products until 1 January 2016, without prejudice to the right of LDCs 'to seek other extensions of the transition periods as provided for

⁸⁷ Doha Declaration (n 64) Paragraph 6.

⁸⁸ The eligibility of WTO member states to make use of the waiver is further elaborated in in note 379 to sub-chapter 2.4.3.8.

⁸⁹ WTO, 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of 30 August 2003' (2 September 2003) WTO Doc WT/L/540, paras 2 and 3; WTO, 'WTO Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' <https://www.who.int/medicines/areas/policy/wto_impl_para6/en/> accessed 1 May 2019.

⁹⁰ Lucyk S (n 40) 199.

⁹¹ WTO, 'Amendment of the TRIPS Agreement: Decision of 6 December 2005' (8 December 2005) WTO Doc WT/L/641; cf. Lucyk S (n 40) 200.

⁹² Lucyk S (n 40) 200.

⁹³ WTO, 'WTO IP rules amended to ease poor countries' access to affordable medicines' <https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm> accessed 1 May 2019.

⁹⁴ Doha Declaration (n 64) Paragraph 7.

in Article 66.1 of the TRIPS Agreement.⁹⁵ Subsequently, this waiver was further extended until 1 January 2033, as discussed below in 2.4.5.

In conclusion, the Doha Declaration can be regarded as a considerable political achievement of developing countries, highlighting the importance of protecting public health.⁹⁶ In this respect, the Doha Declaration provides a clarification of the relationship between the TRIPS Agreement and public health, thereby addressing urgent problems faced by many developing countries.⁹⁷ In particular, the declaration defines some of the flexibilities of the TRIPS Agreement and reaffirms the right of WTO member states to adopt measures for the protection of public health.⁹⁸ Furthermore, the way in which the Doha Declaration addresses pharmaceutical products implies that differential treatment of certain fields of technology is possible under TRIPS,⁹⁹ even though Article 27(1) explicitly prohibits discrimination as to the field of technology, as elaborated below in 2.4.3.1. Ultimately, the Doha Declaration can be regarded as an important tool, providing guidance on how the TRIPS Agreement can be interpreted in a manner conducive to public health.

2.4 Interpretation of Pharmaceutical Patent Rights under the TRIPS Patent Regime in Light of the Doha Declaration

Of the IP regulations provided by TRIPS, the international harmonisation of patent laws seems to have the most significant economic impact on developing countries.¹⁰⁰ In this regard, the following section of this chapter provides a brief interpretation of the TRIPS Agreement in context of the Doha Declaration, focussing on patent standards and other interrelated regulations relevant for understanding the impact of pharmaceutical patents on the accessibility of medicines and public health. Due to the constraints of this thesis, this analysis is limited in scope and can only introduce the provisions of the TRIPS Agreement. Furthermore, after providing a brief introduction of the WTO Dispute Settlement Understanding (DSU) to indicate the strong

⁹⁵ *ibid.*

⁹⁶ Lucyk S (n 40) 194.

⁹⁷ Correa CM, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (n 57) 48.

⁹⁸ *ibid.*

⁹⁹ *ibid* 42.

¹⁰⁰ UNCTAD-ICTSD (n 35) 363.

enforceability of the TRIPS patent regime, this analysis will primarily address the substantive provisions of TRIPS, leaving regulations on procedural requirements, predominantly unaddressed, due to their limited relevance for the scope of this research. It is further important to note that the provisions of the TRIPS Agreement are not necessarily addressed in chronological order here, but instead enumerated in a way that provides an easy and coherent understanding of interrelated regulations.

2.4.1 The WTO Dispute Settlement Understanding (DSU)

The Dispute Settlement Understanding (DSU), as found in Annex 2 of the WTO Agreement,¹⁰¹ is one of the central pillars of the WTO, upholding the rule of law by ensuring that in situations of dispute WTO rules can be effectively enforced.¹⁰² The purpose of the DSU is to ‘provide security and predictability [...], and to clarify the existing provisions of [WTO] agreements in accordance with customary rules of interpretation of public international law.’¹⁰³ The ultimate aim of the DSU, however, is not to issue judgments, though it may do so, but to find mutually acceptable solutions through consultation and mediation.¹⁰⁴ It must be noted that while the DSU addresses specific issues between disputing parties, its findings do not create precedents, meaning that future panels are not bound by former decisions even where disputes concern the same subject matter.¹⁰⁵ While according to Article 1(1) of Annex 2 the DSU is only applicable to disputes concerning WTO agreements, the law covered in DSU proceedings is not limited to those agreements.¹⁰⁶ In the context of this thesis, it is relevant to provide a condensed overview of the DSU for a better understanding of the enforceability of WTO trade agreements, including the TRIPS patent regime,

¹⁰¹ The abbreviation DSU refers to the WTO Dispute Settlement Understanding which is regulated by the ‘Understanding on Rules and Procedures Governing the Settlement of Disputes’ in Annex 2 of the WTO Agreement, which is also abbreviated as DSU. As the context of the Dispute Settlement Understanding in this thesis is always connected to Annex 2 of the WTO Agreement, both abbreviations of DSU are used synonymously.

¹⁰² WTO, ‘Understanding the WTO: Settling Disputes: A Unique Contribution’
<https://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm> accessed 1 May 2019.

¹⁰³ Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the Marrakesh Agreement Establishing the World Trade Organization (signed 15 April 1994, entered into force 1 January 1995) [DSU], Article 3(2).

¹⁰⁴ WTO, ‘Understanding the WTO: Settling Disputes: A Unique Contribution’ (n 102).

¹⁰⁵ WTO, ‘Legal effect of panel and appellate body reports and DSB recommendations and rulings’
<https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c7s2p1_e.htm> accessed 2 May 2019.

¹⁰⁶ cf. Sellin J (n 35) 155.

which will be of further relevance when scrutinising the potential existence of a hierarchy between different international treaty regimes, in chapter 3.1.

The applicability of the WTO DSU to disputes under the TRIPS Agreement is established in Article 64(1) TRIPS.¹⁰⁷ In brief, for disputes arising from the TRIPS Agreement, the DSU typically addresses violation complaints, with the rationale of protecting the reasonable expectations of WTO member states relating to ‘the competitive relationship between their own and foreign products.’¹⁰⁸ This competitive relationship is considered to be disrupted when a violation of a WTO obligation leads to an impairment or nullification of the benefits provided by the WTO trading system.¹⁰⁹ If a violation can be proven, it is generally assumed that this leads to an impairment or nullification of these benefits, without the need for the claimant to prove that the violation actually led to such an impairment.¹¹⁰ The burden of proof then lies with the responding member state, which is required to either demonstrate that a violation of a WTO obligation does not result in an impairment of the benefits of the claimant,¹¹¹ or to legitimise its violation by proving an appropriate justification, as for example found in the TRIPS exceptions and flexibilities.¹¹² If a member state is ultimately found to be in violation of a WTO obligation, that member is required to amend inconsistent measures so that they comply with WTO obligations.¹¹³ If the responding member fails or refuses to comply with the decisions of a DSU panel within a reasonable time frame, the WTO can impose sanctions in the form of mutually agreed compensation, or a temporary suspension of trade or other concessions.¹¹⁴

The possibility for the DSU to directly impose sanctions on member states for violations of WTO agreements, provides a comparatively strong enforcement

¹⁰⁷ TRIPS Agreement (n 32) Article 64(1).

¹⁰⁸ Sellin J (n 35) 157; UNCTAD-ICTSD (n 35) 664.

¹⁰⁹ UNCTAD-ICTSD (n 35) 664; cf. Sellin J (n 35) 157.

¹¹⁰ Sellin J (n 35) 157; UNCTAD-ICTSD (n 35) 665-666.

¹¹¹ In reality, historic GATT and WTO dispute settlements indicate considerable difficulties for respondents to prove that a violation does not lead to an impairment of the expected benefits, so that an effective defence commonly requires the respondent to prove that a violation has not occurred in the first place. See thereto: UNCTAD-ICTSD (n 35) 666.

¹¹² UNCTAD-ICTSD (n 35) 665-666; Sellin Book p. 157.

¹¹³ Sellin J (n 35) 157.

¹¹⁴ DSU (n 103) Article 22(2); Sellin J (n 35) 157; UNCTAD-ICTSD (n 35) 667-668.

mechanism¹¹⁵ under international law.¹¹⁶ At the same time, however, the DSU safeguards that remedial actions are based on justified reasons, in that Article 23(1) DSU provides:

When Members seek the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements or an impediment to the attainment of any objective of the covered agreements, they shall have recourse to, *and abide by*, the rules and procedures of this Understanding.¹¹⁷ (*emphasis added*)

The requirement that members abide by the rules of the DSU establishes that the WTO DSU is mandatory for addressing violations of, inter alia, the TRIPS Agreement, suggesting that unilateral measures to remedy a violation – such as unilateral trade sanctions, or economic or political pressure – are not permissible.¹¹⁸ While on first glance, this seems to protect developing countries from unjustified unilateral measures, the threat to invoke the DSU itself may be utilised to influence policy decisions of economically less powerful countries. In particular, developing country governments may refrain from adopting public health policies, if there is a realistic risk of facing expensive litigation, and the possibility of becoming liable to remuneration payments.¹¹⁹

¹¹⁵ The WTO DSU constitutes a considerably stronger enforcement mechanism than usually provided for by international treaty regimes, in particular, when compared to the relatively weak enforcement mechanisms available under international human rights law, as further elaborated in chapters 3.1.1.3 and 3.1.2.1.

¹¹⁶ de Feyter K, *Human Rights: Social Justice in the Age of the Market* (Zed Books 2005) 8.

¹¹⁷ DSU (n 103) Article 23(1).

¹¹⁸ cf. Sellin J (n 35) 158.

¹¹⁹ Kapczynski A, ‘The Trans-Pacific Partnership - Is It Bad for Your Health?’ (2015) 373 *The New England Journal of Medicine* 201, 202; Ruckert A, Schram A, and Labonte R, ‘The Trans-Pacific Partnership Agreement: Trading away our health?’ (2015) 106 *Canadian Journal of Public Health* 249, 250; Stuhldreier M, ‘The Trans-Pacific Partnership Agreement and its Threats to the Affordability of Medical Products in Developing Countries’ (2016) 19 *Trinity C.L. Rev.* 175, 189. My article – Stuhldreier M, ‘The Trans-Pacific Partnership Agreement and its Threats to the Affordability of Medical Products in Developing Countries’ – was published during the first year of my PhD studies, and is attached in the appendix to this thesis.

2.4.2 General Provisions and Basic Principles under Part I TRIPS

2.4.2.1 Article 1: Minimum Protection Standards

Article 1 TRIPS identifies the nature and scope of the provisions of the agreement, stipulating in paragraph 1 that WTO members ‘shall give effect to the provisions of this Agreement.’¹²⁰ The third sentence of Article 1(1) determines the freedom of member states to implement the TRIPS provisions in a manner appropriate for ‘their own legal system and practice.’¹²¹ On the one hand, this determination indicates that the TRIPS Agreement is not of direct effect, and therefore necessitates the implementation into national law.¹²² On the other hand, this provision grants WTO members the freedom to implement the agreement in a way suitable for their individual needs, making use of the flexibilities provided under TRIPS.¹²³

Of particular importance for the scope of this thesis is the second sentence of Article 1(1) TRIPS, which reads:

Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.¹²⁴

This provision establishes what is commonly referred to as TRIPS minimum standards. As indicated above in 2.2, WTO members are free to implement stronger levels of IP protection, but are not allowed to provide a lesser degree of protection than that required by TRIPS.¹²⁵ The minimum standards thus have to be implemented regardless the level of a WTO member’s development,¹²⁶ subject, however, to the transitional periods provided for in TRIPS, as elaborated below in 2.4.5. Of further importance is the qualification of Article 1(1) that members ‘shall not be obliged’ to implement more extensive IP protection than the minimum standards.¹²⁷ This expression indicates the illegitimacy of practices that pressure WTO members into

¹²⁰ TRIPS Agreement (n 32) Article 1(1).

¹²¹ *ibid.*

¹²² UNCTAD-ICTSD (n 35) 17.

¹²³ *ibid* 17-18.

¹²⁴ TRIPS Agreement (n 32) Article 1(1).

¹²⁵ UNCTAD-ICTSD (n 35) 24.

¹²⁶ Sellin J (n 35) 162.

¹²⁷ TRIPS Agreement (n 32) Article 1(1).

conceding to the adoption of stronger IP protection standards in bilateral or multilateral trade agreements – which is common practice in TRIPS-Plus agreements, as elaborated below in 2.5 – as such practices disregard the requirement that WTO members shall not be obliged to implement more extensive protection.¹²⁸

2.4.2.2 Article 6: Exhaustion

Article 6 TRIPS addresses issues regarding the exhaustion of IP rights. In essence, the principle of exhaustion establishes that once a product which is protected by an IP right¹²⁹ legitimately enters the market, *that specific product* is no longer protected by the exclusive rights of the right holder.¹³⁰ The rationale behind the exhaustion of rights is that after an IP rights holder makes a first sale of a product, he/she is economically compensated for his/her innovative efforts in regard to that specific product.¹³¹ With the transfer of a good, the purchaser thus receives the right to freely use and dispose of that product without restriction.¹³² The exhaustion of IP rights, however, does not impact the right of an IP right holder to prevent others from making a protected product, meaning the manufacturing of generic copies remains subject to authorisation by the rights holder.¹³³

Generally, three systems of exhaustion can be identified. The first is the principle of national exhaustion, the second is the principle of regional exhaustion, and the third is the principle of international exhaustion. The principle of national exhaustion provides that once a product is placed on the domestic market, the IP rights holder can no longer

¹²⁸ UNCTAD-ICTSD (n 35) 24.

¹²⁹ The question of when a product is legitimately placed on a market is not conclusively answered by international IP laws. In particular, there are controversies concerning whether goods manufactured under a compulsory license can be considered as legitimately placed on the market. It may be argued that by providing adequate compensation to an IP rights holder for products manufactured under a compulsory license, the legitimate economic interests of the rights holder in respect of those products are satisfied. A different view proposes that in order for a product to be legitimately placed on the market, the consent of the rights holder is required, meaning either that the right holder himself places the product on the market by selling it, or that a product is placed on the market in accordance with a (voluntary) licensee granted by the rights holder. See thereto: Correa CM, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (OUP 2007) 84-85; Gervais DJ, *The TRIPS Agreement: Drafting History and Analysis* (4th edn, Sweet & Maxwell 2012) para 2.99.

¹³⁰ Sellin J (n 35) 165-166.

¹³¹ UNCTAD-ICTSD (n 35) 93.

¹³² *ibid.*

¹³³ *ibid.*

control sales of that specific product within the domestic market.¹³⁴ Similarly, the principle of regional exhaustion provides that once a product is placed on a regional market, the IP right holder can no longer control sales of this specific product within the trade region, as for example adopted in the EU.¹³⁵ In contrast, the principle of international exhaustion provides that once a product is legally placed on a market anywhere in the world, the IP rights holder can no longer control importation and sales of that specific product in any country that adopts this principle of exhaustion.¹³⁶ The principle of international exhaustion opens up the possibility of parallel trade, i.e. the parallel importation of products legally placed on another market, without the authorisation of the IP rights holder.¹³⁷

In regard to the domestic implementation of an exhaustion system, Article 6 TRIPS provides:

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.¹³⁸

By exempting issues of exhaustion from the WTO DSU, the TRIPS Agreement provides a flexibility for WTO member states to determine their own preferred way of dealing with issues of exhaustion, indicating that members are free to choose any principles, subject to the non-discrimination requirements of Articles 3 and 4 TRIPS. This interpretation, however, is not undisputed. In the field of patents, Article 28(1) TRIPS provides that a patent holder can prevent third parties from importing a patented product or a product produced using a patented process, as elaborated below in 2.4.3.3.¹³⁹ It may therefore be argued that a system of international exhaustion, which facilitates parallel importation, would violate the right to prevent the importation of patented products.¹⁴⁰ It can be suggested, however, that the exhaustion of rights defines

¹³⁴ Sellin J (n 35) 166.

¹³⁵ Saggi K, 'Regional exhaustion of intellectual property' (2014) 10 *International Journal of Economic Theory* 125, 126.

The principle of regional exhaustion, however, may arguably amount to an infringement of the MFN treatment under Article 4 TRIPS, by treating WTO members within a region differently than members outside the region. See thereto: Gervais DJ, *The TRIPS Agreement* (n 129) para 2.102; Saggi K (n 135) 126.

¹³⁶ UNCTAD-ICTSD (n 35) 93.

¹³⁷ Correa CM, *A commentary on the TRIPS Agreement* (n 129) 78.

¹³⁸ TRIPS Agreement (n 32) Article 6.

¹³⁹ *ibid* Article 28(1).

¹⁴⁰ cf. UNCTAD-ICTSD (n 35) 94.

an end to IP protection claims, including those of Article 28, in that the legitimate interests of the IP rights holder are fulfilled with respect to the specific product. It therefore seems likely that the international exhaustion principle can be applied alongside Article 28 without contradiction. Additionally, Footnote 6 to Article 28 TRIPS explicitly provides that the conferred rights ‘in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.’¹⁴¹ The controversy regarding legitimate principles of exhaustion was further addressed by the Doha Declaration, which settled any dispute by reaffirming in Paragraph 5(d):

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.¹⁴²

This reaffirmation is of particular relevance, as the right to facilitate parallel importation under the principle of international exhaustion has been considered by many developing countries as a key element for protecting public health, because pharmaceutical products can be imported from countries where they are available at a lower price.¹⁴³ In the context of pharmaceutical products, however, parallel importation can have negative impacts as well. A common practice of pharmaceutical corporations is to offer certain medications at cheaper prices on markets in developing countries and LDCs.¹⁴⁴ Permitting parallel trade, may then have the negative impact that pharmaceutical corporations refrain from such differential pricing strategies, to prevent lower priced medicines from entering wealthy markets.¹⁴⁵ According to Correa, however, the risk of cheaper medicines from developing countries entering developed markets is often overstated, as parallel importation is only worthwhile when price differences are significant, and because developed countries can further take measures, consistent with WTO rules, to restrict such parallel imports.¹⁴⁶

¹⁴¹ TRIPS Agreement (n 32) Footnote 6 to Article 28; see thereto: Correa CM, *A commentary on the TRIPS Agreement* (n 129) 82.

¹⁴² Doha Declaration (n 64) Paragraph 5(d).

¹⁴³ Correa CM, *A commentary on the TRIPS Agreement* (n 129) 80.

¹⁴⁴ cf. Sellin J (n 35) 191.

¹⁴⁵ Correa CM, *A commentary on the TRIPS Agreement* (n 129) 88.

¹⁴⁶ *ibid* 88-89.

2.4.2.3 Articles 7 and 8, and the Preamble: Objectives and Principles

The objectives and principles of TRIPS are established in the agreement's preamble, as well as in its main provisions in Articles 7 and 8, indicating that the objectives and principles are aimed at creating direct rights and obligations.¹⁴⁷ This is of major importance, as it elevates the scope of the principles and objectives from being merely interpretative guidelines¹⁴⁸ to being an integral part of the agreement itself.

Generally speaking, by reflecting the intentions of the negotiating parties, the preamble of TRIPS is of particular relevance for identifying the agreement's teleological purpose. In regard to the relation between the patentability of medical products and the right to health, paragraphs 1, 4, 5, and 6 of the preamble are of particular relevance for the context of this thesis. Paragraph 1 establishes the main purpose of the TRIPS IP regime as the reduction of 'distortions and impediments to international trade' by promoting 'effective and adequate protections' of IP rights, recognising, however, the possibility that excessive IP protection can become a barrier to legitimate trade itself.¹⁴⁹ This acknowledgement reaffirms that the protection of IP rights is not an end in itself. According to the WTO Agreement, the WTO rather aims to promote trade and economic development, and not merely the protection of private interests of rights holders.¹⁵⁰ In this regard, paragraph 4 of the preamble of TRIPS defines IP rights as private rights, which can be of importance when these private rights have to be balanced against greater public interests, such as the protection of public health.¹⁵¹ In this consideration, paragraph 5 of the preamble recognises that IP rights are subject to 'public policy objectives' of WTO member states, including, inter alia, developmental objectives.¹⁵² Paragraph 6 of the preamble then further recognises the special needs of

¹⁴⁷ UNCTAD-ICTSD (n 35) 118-119.

¹⁴⁸ The preamble of an agreement commonly reflects the nature of negotiations and elaborates the intention of the parties entering such negotiations. In this consideration, a preamble provides interpretative guideline for the implementation of an agreement and the settlement of disputes in cases of ambiguity. This is in accordance with Article 31(2) VCLT which stipulates that the preamble is an integral part for the purpose of interpreting a treaty, as the context shall comprise, inter alia, the text of the treaty, including its preamble and annexes. See thereto: UNCTAD-ICTSD (n 35) 2; VCLT (n 65) Article 31(2).

¹⁴⁹ TRIPS Agreement (n 32) Preamble para 1; cf. Gervais DJ, *The TRIPS Agreement* (n 129) para 2.10.

¹⁵⁰ UNCTAD-ICTSD (n 35) 10.

¹⁵¹ TRIPS Agreement (n 32) Preamble para 4; Gervais DJ, *The TRIPS Agreement* (n 129) para 2.11.

¹⁵² TRIPS Agreement (n 32) Preamble para 5.

LDCs, and the necessity of maximum flexibility for the domestic implementation of the TRIPS Agreement.¹⁵³

In essence, the preamble of the TRIPS Agreement thus indicates that IP rights serve a higher purpose than the simple protection of rights holders. By promoting innovation, IP rights should particularly facilitate international trade and economic development, and thereby, in accordance with the core objective of the WTO, improve standards of living.¹⁵⁴ In this consideration, the preamble confirms the need to strike a balance between the protection of IP rights and free trade, between the developed world and developing countries, and, not least, between private IP rights and higher public interests.¹⁵⁵

The necessity to balance rights and obligations is therefore explicitly integrated in the main text of the TRIPS Agreement, in Article 7. It must be noted, however, that while TRIPS quite clearly defines the rights of IP rights holders, concomitant obligations are commonly not further elaborated by the agreement.¹⁵⁶ The general existence of obligations is nevertheless confirmed by Article 7, which outlines the objectives of the agreement, providing:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.¹⁵⁷

This provision again reaffirms that IP rights under TRIPS are not an end in themselves, but that they are a means to achieve the objectives set out in Article 7.¹⁵⁸ In particular, the promotion of innovation, and the transfer and dissemination of technology should serve wider public policy objectives, including social and economic welfare.¹⁵⁹ The use of the term ‘should’ in Article 7, however, indicates that IP rights do not automatically fulfil these objectives.¹⁶⁰ In this respect, it is of vital importance that the national implementation of the TRIPS Agreement is conducted in a manner that gives

¹⁵³ *ibid* Preamble para 6.

¹⁵⁴ *cf.* UNCTAD-ICTSD (n 35) 13.

¹⁵⁵ Gervais DJ, *The TRIPS Agreement* (n 129) para 2.12.

¹⁵⁶ Correa CM, *A commentary on the TRIPS Agreement* (n 129) 101.

¹⁵⁷ TRIPS Agreement (n 32) Article 7.

¹⁵⁸ UNCTAD-ICTSD (n 35) 125-126.

¹⁵⁹ Correa CM, *A commentary on the TRIPS Agreement* (n 129) 94.

¹⁶⁰ UNCTAD-ICTSD (n 35) 126.

effect to an adequate balance of private and public interests.¹⁶¹ This is of particular importance, as IP rights are liable to impact on the enjoyment of human rights. While the UN argues that the WTO is bound by human rights laws, human rights concerns are not directly expressed by the TRIPS Agreement.¹⁶² This could be remedied by a balanced implementation of the agreement, which should therefore pay due regard to human rights considerations in domestic IP laws.

While Article 7 indicates the importance of striking a balance, the TRIPS Agreement does not further elaborate on the ways in which an adequate balance can be achieved.¹⁶³ Consequently, Article 7 must be seen as a guideline providing context for the interpretation of other TRIPS provisions.¹⁶⁴ This was confirmed by the WTO panel in the *Canada – Patent Protection of Pharmaceutical Products* case,¹⁶⁵ and further reaffirmed by the Doha Declaration providing in Paragraph 5(a) that ‘each provision of the TRIPS Agreement shall be read in light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles’, i.e. Articles 7 and 8.¹⁶⁶ Therefore, Article 7 is of particular relevance for the interpretation of insufficiently defined obligations and exceptions, and undefined terms,¹⁶⁷ as well as for establishing whether the current international patent regime can be regarded as justified in chapter 4.

Article 8 TRIPS establishes the core principles of the agreement. To this end, Article 8(1) explicitly facilitates the adoption of internal measures¹⁶⁸ for the protection of public health, further referring to sectors of vital importance to socio economic development, providing:

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.¹⁶⁹

¹⁶¹ *ibid.*

¹⁶² Correa CM, *A commentary on the TRIPS Agreement* (n 129) 99-100.

¹⁶³ *ibid* 101.

¹⁶⁴ *ibid* 93.

¹⁶⁵ *cf. ibid* 93-94.

¹⁶⁶ Doha Declaration (n 64) Paragraph 5(a); *cf. Correa CM, A commentary on the TRIPS Agreement* (n 129) 103.

¹⁶⁷ Correa CM, *A commentary on the TRIPS Agreement* (n 129) 94-95.

¹⁶⁸ *cf. UNCTAD-ICTSD* (n 35) 126.

¹⁶⁹ TRIPS Agreement (n 32) Article 8(1).

Similar to Article 8(1), Article 8(2) TRIPS allows for the adoption of measures to prevent or remedy the abuse of IP rights by rights holders, provided that such measures are consistent with the provisions of the TRIPS Agreement.¹⁷⁰

Article 8 is more strongly formulated than Article 7 and, contrary to Article 7, allows members to take specific action.¹⁷¹ WTO member states have considerable leeway in implementing Article 8(1), as TRIPS leaves the scope of the term ‘public interest’ undefined.¹⁷² However, any action taken under the provisions of Article 8 has to be necessary to achieve the stated purpose,¹⁷³ and must be administered in the form of laws or regulations.¹⁷⁴ While the adopted measures have to be consistent with the provisions of the TRIPS Agreement, it seems that Article 8 at least allows for the maximum use of the flexibilities and exceptions provided for by TRIPS.¹⁷⁵ To assess the legitimacy of a measure taken under Article 8, Article 7 and the preamble have to be taken into consideration, with particular regard to the requirement of striking a balance between rights and obligations, and socio-economic welfare.¹⁷⁶ Nothing in the TRIPS Agreement should then prevent members from protecting public health or promoting other vital public policies as defined in Article 8, so long as the measures are adopted in good faith.¹⁷⁷

This interpretation was reaffirmed by paragraph 4 of the Doha Declaration, stipulating ‘that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health’, and ‘that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.’¹⁷⁸ Thereby, as indicated above in 2.3, the Doha Declaration made public health a stated purpose of the TRIPS Agreement.¹⁷⁹ It has been further argued that legitimate measures for the protection of public health and the public interest are not limited to the flexibilities and exceptions provided by the TRIPS Agreement, but may include

¹⁷⁰ cf. Correa CM, *A commentary on the TRIPS Agreement* (n 129) 110; UNCTAD-ICTSD (n 35) 127.

¹⁷¹ Gervais DJ, *The TRIPS Agreement* (n 129) para 2.123.

¹⁷² Correa CM, *A commentary on the TRIPS Agreement* (n 129) 105.

¹⁷³ Gervais DJ, *The TRIPS Agreement* (n 129) para 2.124.

¹⁷⁴ Sellin J (n 35) 168.

¹⁷⁵ cf. Correa CM, *A commentary on the TRIPS Agreement* (n 129) 104.

¹⁷⁶ *ibid.*

¹⁷⁷ *ibid.*; UNCTAD-ICTSD (n 35) 127.

¹⁷⁸ Doha Declaration (n 64) Paragraph 4.

¹⁷⁹ Correa CM, *A commentary on the TRIPS Agreement* (n 129) 109.

other measures related to the use of IP rights as well.¹⁸⁰ In this regard, the purpose of paragraph 4 of the Doha Declaration indicates that certain derogations from TRIPS provisions seem to be justified if they serve the purpose of Article 8.¹⁸¹ The Doha Declaration, however, does not explicitly provide that TRIPS provisions may be overridden, but rather stipulates that a maximum use of flexibilities and exceptions provided for in TRIPS must be available for the protection of public health, with the agreement's objectives and principles determining their justification.¹⁸² Therefore, Article 8 itself does not justify the creation of new exceptions.¹⁸³ Article 8 thus rather provides a rationale for the flexibilities and exceptions provided by TRIPS, and, like Article 7, constitutes an interpretative guideline.¹⁸⁴

In summary, Articles 7 and 8 stipulate the right of WTO members to implement the TRIPS Agreement in a way suitable to their specific needs, their public policy objectives, and their general social and economic welfare.¹⁸⁵ In concordance with the Doha Declaration, the objectives and principles particularly provide developing countries with the right to make full use of the flexibilities in TRIPS to protect public health and access to medicines, without, however, constituting a general exception in themselves.¹⁸⁶

2.4.3 Substantive Patent Law Provisions under Part II Section 5 TRIPS

2.4.3.1 Article 27: Patentable Subject Matter

Article 27 TRIPS is the first international regulation on the substantive elements of patent laws, providing minimum standards on patentable subject matter and conditions for patentability,¹⁸⁷ providing:

¹⁸⁰ *ibid* 104.

¹⁸¹ *ibid* 108-109.

¹⁸² UNCTAD-ICTSD (n 35) 131-132.

¹⁸³ Gervais DJ, *The TRIPS Agreement* (n 129) para 2.123.

¹⁸⁴ *ibid*.

¹⁸⁵ Correa CM, *A commentary on the TRIPS Agreement* (n 129) 103.

¹⁸⁶ Sellin J (n 35) 169.

¹⁸⁷ *ibid* 176.

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.¹⁸⁸ (*footnote omitted*)

In essence, this provision mandates the availability of patents for all types of product and process inventions.¹⁸⁹ In particular, the non-discrimination principle as to the field of technology stipulates that patents must be made available in all industrial sectors, including for pharmaceutical products.¹⁹⁰ The TRIPS Agreement thus constitutes an intensification of international patent standards, as prior patent treaties, such as the Paris Convention, did not establish specific patentability criteria and allowed for exclusions from patentability.¹⁹¹ Notably, before the TRIPS Agreement was concluded, about 50 countries did not provide for the patentability of pharmaceutical products.¹⁹²

The non-discrimination principle aims at the protection of rights holders from arbitrary policies,¹⁹³ and is limited to the grounds provided for by Article 27(1), namely the place of invention, the field of technology, and whether products are imported or produced locally.¹⁹⁴ This principle is a new development in international patent laws, providing that patent standards must not be discriminatory with regard to the availability of patents, and their enjoyment.¹⁹⁵ It follows that patent periods, for example, may not differ for different fields of technology, nor may the patentability requirements vary between different fields.¹⁹⁶ The non-discrimination principle, however, may not be regarded as absolute.¹⁹⁷ In the *Canada – Patent Protection of Pharmaceutical Products* case, the WTO panel explicitly distinguished between

¹⁸⁸ TRIPS Agreement (n 32) Article 27(1).

¹⁸⁹ UNCTAD-ICTSD (n 35) 353.

¹⁹⁰ cf. *ibid*; Hestermeyer H (n 54) 55.

¹⁹¹ UNCTAD-ICTSD (n 35) 354.

¹⁹² *ibid* 353.

¹⁹³ *ibid* 374.

¹⁹⁴ TRIPS Agreement (n 32) Article 27(1); UNCTAD-ICTSD (n 35) 368-369.

¹⁹⁵ UNCTAD-ICTSD (n 35) 368.

¹⁹⁶ *ibid*.

¹⁹⁷ *ibid*.

discrimination and differential treatment.¹⁹⁸ In this regard, differential treatment of certain fields of technology can be regarded as legitimate, as long as patents for all fields of technology are generally available, and the differentiation is not discriminatory.¹⁹⁹ In certain circumstances, a differentiation between different fields of technology may even be desirable.²⁰⁰ In this respect, the panel indicated that different rules can be applied to different fields of technology, as long as such differentiations are adopted for *bona fide* purposes,²⁰¹ arguing that ‘Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas.’²⁰² This view was implicitly reaffirmed in the Doha Declaration, specifically addressing pharmaceutical products in paragraphs 6 and 7, seeking a specific solution for issues connected to this field of technology.²⁰³

While Article 27(1) requires the availability of patents for products and processes in all fields of technology, the patentability of a specific product or process is subject to certain conditions. In particular, TRIPS only stipulates that patents shall be available for inventions, so that mere discoveries, i.e. substances that exist in nature, can – but do not have to – be excluded.²⁰⁴ Further requirements for the patentability of an invention are established by Article 27(1) in the criteria of novelty, the involvement of an inventive step, and the capability of industrial application.²⁰⁵ In accordance with Article 1(1) TRIPS, WTO members have considerable freedom for implementing these criteria in a way appropriate for their specific needs, subject to certain basic definitions.²⁰⁶

The novelty requirement simply necessitates that an invention is new, meaning that before the date of a patent application, i.e. the priority date, no information about this invention is publicly available.²⁰⁷ In accordance with Article 29 TRIPS, as elaborated below in 2.4.3.2, the rationale for this requirement is that the granting of a patent is

¹⁹⁸ WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products* (17 March 2000) WT/DS114/R, para 7.94.

¹⁹⁹ Gervais DJ, *The TRIPS Agreement* (n 129) para 2.358.

²⁰⁰ *ibid.*

²⁰¹ UNCTAD-ICTSD (n 35) 370-371.

²⁰² WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products* (n 198) para 7.92.

²⁰³ cf. Doha Declaration (n 64) Paragraphs 6 and 7; Gervais DJ, *The TRIPS Agreement* (n 129) para 2.367ff.

²⁰⁴ cf. Hestermeyer H (n 54) 54; UNCTAD-ICTSD (n 35) 357.

²⁰⁵ TRIPS Agreement (n 32) Article 27(1).

²⁰⁶ UNCTAD-ICTSD (n 35) 358.

²⁰⁷ *ibid* 359.

subject to the disclosure of something new.²⁰⁸ In order to determine information as new, rather than as part of the prior art, such information must not have been disclosed anywhere in the world.²⁰⁹ A prior secret use of such information, without public disclosure, however, does not adversely impact upon patentability in regard to novelty considerations.²¹⁰

The requirement of an inventive step stipulates that additionally to being new, an invention must constitute an advancement over prior art.²¹¹ Footnote 5 to Article 27(1) further defines the term ‘inventive step’ as being synonymous to the term ‘non-obvious’.²¹² As the requirement of inventiveness, however, is not defined in further detail by the TRIPS Agreement, WTO members are free to determine their own level of inventiveness required for the grant of a patent.²¹³ Developing countries can utilise this leeway to implement a system which is appropriate for their needs by setting high inventiveness requirements, preventing the patentability of incremental developments.²¹⁴ An adequate implementation of the inventive step requirement, suitable to the needs of each WTO member, can thus be used to mitigate negative impacts and to prevent the ‘evergreening’ of patents.²¹⁵ Patent evergreening is the use of strategic measures to create a perpetuation of the benefits of patent protection, by disclosing information in a way that facilitates the acquisition of successive patents. While one possibility of achieving this goal is the patenting of new uses of known products, as established by a number of TRIPS-Plus agreements discussed below in 2.5.1.1, the patenting of incremental developments, i.e. innovations that are not truly new or inventive, can lead to the same effect.²¹⁶

The capability of industrial application requirement is relatively straight forward, simply providing that an invention must be of use for any kind of industry.²¹⁷ In this regard, footnote 5 to Article 27(1) defines the term ‘industrial application’ as being synonymous with the term ‘useful’. Subject to national implementation, it thus seems

²⁰⁸ *ibid.*

²⁰⁹ *cf. ibid*; Hestermeyer H (n 54) 65.

²¹⁰ UNCTAD-ICTSD (n 35) 359.

²¹¹ *ibid.*

²¹² TRIPS Agreement (n 32) Footnote 5 to Article 27(1).

²¹³ Sellin J (n 35) 186-187.

²¹⁴ UNCTAD-ICTSD (n 35) 360.

²¹⁵ Sellin J (n 35) 187.

²¹⁶ *cf. ibid*; Stuhldreier M (n 119) 183.

²¹⁷ UNCTAD-ICTSD (n 35) 361.

to be clear that product innovations which can be manufactured, and process innovations which can be used to produce goods, such as pharmaceuticals, fulfil this requirement.

Paragraph 1 of Article 27 is subject to paragraphs 2 and 3 which provide optional exceptions that override the general requirements of paragraph 1, if provided for by domestic patent laws.²¹⁸ In this respect, Article 27(2) allows members to exclude products from patentability, as necessary for the protection of *ordre public* or morality, explicitly including the protection of human life and health.²¹⁹ In this regard, it may be asked whether the protection of human health would allow a general exclusion of pharmaceutical products from patentability.²²⁰ Article 27(2), however, only addresses specific inventions, rather than categories of inventions.²²¹ Furthermore, the applicability of Article 27(2) requires that the protection of *ordre public* or morality necessitates the complete prevention of the commercial exploitation of a product, i.e. its general availability on the market.²²² Therefore, Article 27(2) is not applicable for generally excluding pharmaceutical products from patentability.²²³

Article 27(3) provides a list of focussed exclusions from patentability that do not need to be justified in the same strict way as the exclusions provided under Article 27(2). With respect to the protection of human life and health, Article 27(3)(a) allows for the exclusion from patentability for ‘diagnostic, therapeutic and surgical methods for the treatment of humans or animals’.²²⁴ While pharmaceutical products and processes themselves cannot be excluded from patentability under the TRIPS Agreement, certain uses may be considered a method of therapeutic treatment, and may therefore potentially be excluded from patentability.²²⁵ Such an interpretation, however, seems rather controversial, and its analysis exceeds the scope of this thesis.

²¹⁸ *ibid* 356.

²¹⁹ TRIPS Agreement (n 32) Article 27(1).

²²⁰ Hestermeyer H (n 54) 56.

²²¹ Gervais DJ, *The TRIPS Agreement* (n 129) para 2.359.

²²² Hestermeyer H (n 54) 56.

²²³ UNCTAD-ICTSD (n 35) 376.

²²⁴ TRIPS Agreement (n 32) Article 27(3)(a).

²²⁵ cf. Hestermeyer H (n 54) 57; UNCTAD-ICTSD (n 35) 357.

2.4.3.2 Article 29: Disclosure of the Invention

As mentioned above in 2.4.3.1 where the novelty requirement is considered, the granting of a patent is subject to the disclosure of the invention. According to Article 29(1) TRIPS, the disclosure of an invention has to be conducted in a ‘manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art’.²²⁶ Notably, this disclosure requirement can help to identify whether an invention fulfils the patentability requirements.²²⁷ More importantly, however, the complete disclosure of an invention means that the invention can be freely used by everyone once the patent period expires, which can be seen as one of the greatest advantages of patent systems.²²⁸ The disclosure of the invention is fundamental to patent laws, and, by enhancing the public benefit, can to a certain extent counterbalance the exclusive rights granted to patent owners, as further elaborated in chapter 4.3.1.²²⁹ Patents can only fulfil this objective, if the disclosure of an invention is made in an enabling manner.²³⁰ In reality, however, patent applicants regularly aim to only disclose minimal information in order to hamper follow-up inventions by competitors, and to further limit competition even after a patent expires.²³¹ To remedy this behaviour, Article 29(1) provides WTO members with the option to ‘require the applicant to indicate the best mode for carrying out the invention known to the inventor’.²³²

2.4.3.3 Article 28: Rights Conferred

Article 28 TRIPS defines the exclusive rights granted to patent holders, providing minimum protection standards regarding acts of manufacturing and commercialisation of patented products and processes.²³³ The granting of exclusive rights constitutes a basic principle of patent protection, which aims to promote innovation by ensuring that patent holders can obtain significant returns on their investments throughout the patent

²²⁶ TRIPS Agreement (n 32) Article 29(1).

²²⁷ UNCTAD-ICTSD (n 35) 448.

²²⁸ *ibid* 458.

²²⁹ Hestermeyer H (n 54) 67.

²³⁰ *ibid*.

²³¹ cf. Sellin J (n 35) 188.

²³² TRIPS Agreement (n 32) Article 29(1).

²³³ UNCTAD-ICTSD (n 35) 414.

period.²³⁴ In this respect, the WTO panel in the *Canada – Patent Protection of Pharmaceutical Products* case clarified that, for the limited period of the patent term, the rationale of patent rights ‘is to exclude all forms of competition that could detract significantly from the economic returns anticipated’, as otherwise the purpose of patents could not be achieved.²³⁵ It is important to note that the rights conferred by Article 28 TRIPS are negative rights, i.e. rights to prevent other from taking certain actions,²³⁶ they do not, however, include any positive rights.²³⁷ Positive rights to use or market certain products are subject to other specific requirements provided by national laws, such as marketing approval for pharmaceuticals, meaning that the existence of a patent does not automatically stipulate that a product can be legally placed on the market.²³⁸

Paragraph 1 of Article 28 is divided into two sub-paragraphs, each providing an exhaustive list regulating the exclusive rights conferred by product patents and process patents respectively.²³⁹ For product patents, Article 28(1)(a) TRIPS provides that patent owners are entitled ‘to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing’ the patented product.²⁴⁰ Footnote 6 to this paragraph, however, explicitly limits the scope of the rights to prevent the use, sale, and importation or other distribution of patented goods by subjecting these rights to Article 6 TRIPS, and the principle of exhaustion chosen by each state, as elaborated above in 2.4.2.2.²⁴¹

A product patent holder can prevent the production and distribution of any product covered by the patent, irrespective of the process used to make that product.²⁴² The right to prevent any acts of *making* a product generally extends to products that are made for non-commercial use.²⁴³ Therefore, national patent laws commonly provide exceptions allowing the production of patented goods for private non-commercial use, and/or scientific research and educational purposes.²⁴⁴ According to the principle of

²³⁴ cf. *ibid.*

²³⁵ WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products* (n 198) para 7.55.

²³⁶ UNCTAD-ICTSD (n 35) 414.

²³⁷ Hestermeyer H (n 54) 68.

²³⁸ *ibid.*

²³⁹ Sellin J (n 35) 188.

²⁴⁰ TRIPS Agreement (n 32) Article 28(1)(a).

²⁴¹ TRIPS Agreement (n 32) Footnote 6 to Article 28(1)(a).

²⁴² UNCTAD-ICTSD (n 35) 418-419.

²⁴³ *ibid* 419.

²⁴⁴ *ibid.*

exhaustion, the right to prevent the *use* of a patented product does not entail that a patent holder can prevent the use of a product that was legitimately placed on the market.²⁴⁵ This right instead permits the patent owner to bring actions against the user of a counterfeit good, as well as against the manufacturer of such a product.²⁴⁶ Likewise subject to the principle of exhaustion, the rights to prevent the *offering for sale*, the *selling*, and the *importation* of a patented product, grant the patent owner the right to prevent any of these acts without his authorisation in jurisdictions where the product is patented.²⁴⁷

Article 28(1)(b) TRIPS then regulates the exclusive rights granted by process patents. Unlike product patents, process patents do not encompass the right to prevent the making of a product, as long as the product is made without using a patented process.²⁴⁸ This means that if the same product can be manufactured using a different method of production, the patent owner cannot prevent the production and distribution of products made using that different method, unless the product itself is patented as well.²⁴⁹ Preventable acts under paragraph 1(b) are thus limited to ‘using, offering for sale, selling, or importing’ products directly obtained by a patented process without the patent holder’s consent.²⁵⁰ In summary, Article 28(1) provides that product patents can prevent the manufacturing and commercialisation of all generic copies of a patented product, while process patents can only prevent the production and commercialisation of products made using the specific patented process, not, however, of products that merely can be made using that process.²⁵¹ Process patents, however, are not limited to a specific product, but cover all types of products that are made using the patented process.²⁵²

While Article 28(1) TRIPS provides negative rights to prevent others from undertaking certain acts, Article 28(2) provides positive rights, i.e. the rights to assign patents, to transfer them by succession, and to conclude licensing contracts.²⁵³ Patent owners are

²⁴⁵ *ibid.*

²⁴⁶ *ibid.*

²⁴⁷ *ibid.* 420.

²⁴⁸ *ibid.* 420-421.

²⁴⁹ *ibid.*

²⁵⁰ TRIPS Agreement (n 32) Article 28(1)(b).

²⁵¹ UNCTAD-ICTSD (n 35) 421.

²⁵² *cf. ibid.* 427-428.

²⁵³ TRIPS Agreement (n 32) Article 28(2); Correa CM, *A commentary on the TRIPS Agreement* (n 129) 299.

generally not restricted as to the terms on which they transfer their rights, whether in exchange for royalty payments or free of costs.²⁵⁴ Administrative requirements, however, may be imposed by domestic legislation.²⁵⁵ According to the principle of freedom of contract, a patent owner not only has the right to enter into a contract, but further has the right not to enter into a licensing contract.²⁵⁶ As this can be detrimental to the public interest, however, governments can, in specific situations, provide compulsory licenses under Article 31 TRIPS, as elaborated in chapter 2.4.3.7.²⁵⁷

2.4.3.4 Article 33: Term of Protection

Article 33 TRIPS is the first international provision regulating the term of patent protection, requiring that every WTO member state provides for a minimum patent period of 20 years calculated from the date of filing, i.e. from the date a patent application is submitted.²⁵⁸ While this provision should be relatively uncontroversial, in 2000, Article 33 was subject of a dispute between Canada and the United States (US), addressed by the WTO Appellate Body in the *Canada – Term of Patent Protection* case.²⁵⁹ In brief, the US filed a complaint against Canada regarding the term of patent protection provided under Canadian law, which, rather than providing 20 years of protection from the filing date, provided 17 years of protection from the date on which a patent was issued. Canada suggested that a minimum protection period of 20 years from the filing date was nevertheless provided, as the process of reviewing an application and issuing a patent in Canada takes on average five years.²⁶⁰ The Appellate Body, however, established that the interpretation of Article 33 is relatively clear, providing that a 20-year patent period, calculated from the date of filing, must be provided by the law, thereby rejecting Canada's argument.²⁶¹ This interpretation indicates that the patent term under TRIPS does not offer 20 years of effective protection.²⁶² Thus, both the time required for reviewing and issuing a patent, as well

²⁵⁴ UNCTAD-ICTSD (n 35) 422.

²⁵⁵ *ibid.*

²⁵⁶ *ibid.*

²⁵⁷ *ibid.*

²⁵⁸ TRIPS Agreement (n 32) Article 33.

²⁵⁹ WTO Appellate Body Report, *Canada – Term of Patent Protection* (18 September 2000) WT/DS170/AB/R.

²⁶⁰ UNCTAD-ICTSD (n 35) 425-426.

²⁶¹ WTO Appellate Body Report, *Canada – Term of Patent Protection* (n 259) para 85.

²⁶² Sellin J (n 35) 192.

as the time required for the marketing approval of pharmaceutical products count against the initial patent period.²⁶³ While, in accordance with Article 1(1) TRIPS, WTO members may provide longer patent terms to remedy the time lost, no state may be obliged to do so.²⁶⁴ Consequently, the pharmaceutical industry regularly loses years of effective patent protection because of lengthy approval processes, so that industry lobbyists tend to push for longer patent periods in bilateral and multilateral TRIPS-Plus agreements, as further elaborated below in 2.5.1.2.²⁶⁵

2.4.3.5 Article 32: Revocation/Forfeiture

Article 32 TRIPS provides procedural requirements for the revocation and forfeiture of a patent. These requirements simply stipulate that for acts of revocation or forfeiture judicial review shall be available.²⁶⁶ Article 32, however, does not define or limit the legitimate grounds for the revocation or forfeiture of a patent.²⁶⁷ Therefore, WTO members have the freedom to self-determine these grounds in domestic laws, suitable to their needs.²⁶⁸ The forfeiture of a patent could thus, for example, be utilised to sanction abuses of patent rights, such as prohibitive pricing or not-working of a patent.²⁶⁹ Similarly, the revocation of patents may potentially be utilised to facilitate the protection of the public interest.²⁷⁰ Certain limits, however, are imposed by other international treaties. Article 5(A)(3) of the Paris Convention, for example, provides that '[f]orfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses.'²⁷¹ Furthermore, forfeiture and revocation of patents shall only be executed two years after the grant of a first compulsory license.²⁷² It follows that for the purpose of protecting public health against the detrimental impacts of patent rights, the compulsory licensing system provided by Article 31 TRIPS has to be the first measure taken. As elaborated below in 2.4.3.7, however, compulsory licenses are not always adequate for addressing

²⁶³ *ibid.*

²⁶⁴ TRIPS Agreement (n 32) Article 1(1); Sellin J (n 35) 192.

²⁶⁵ *cf.* Sellin J (n 35) 192.

²⁶⁶ TRIPS Agreement (n 32) Article 32.

²⁶⁷ *cf.* UNCTAD-ICTSD (n 35) 414-415 and 422.

²⁶⁸ *cf.* *ibid* 423.

²⁶⁹ *ibid.*

²⁷⁰ *cf.* *ibid.*

²⁷¹ Paris Convention (n 6) Article 5(A)(3).

²⁷² *ibid.*

urgent public health demands in a suitable manner. Thus, the forfeiture of a patent may constitute a further measure to respond to such situations.

2.4.3.6 Article 30: Exceptions to Rights Conferred

The exclusive rights granted by patents under Article 28 TRIPS are not absolute, meaning that under specific circumstances exceptions to those rights are justified.²⁷³ In this consideration, Articles 30 and 31 TRIPS, as well as the newly adopted Article 31*bis*, provide exceptions to the exclusive rights conferred to patent holders.²⁷⁴ In this respect, Article 30 provides general exceptions, while Articles 31 and 31*bis* provide specific exceptions, meaning that Article 30 is only applicable in cases where the exceptions under Article 31 and 31*bis* cannot be utilised.²⁷⁵ It must be noted here that the following sections – on Articles 30, 31, and 31*bis* TRIPS – can merely provide a brief overview of eligible exceptions to the patent rights conferred by TRIPS, due to the constraints of this thesis.²⁷⁶

Article 30 TRIPS provides:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.²⁷⁷

In general, WTO member states are free to legislate on the grounds for which exceptions to patent rights shall be available,²⁷⁸ provided that those exceptions fulfil the three conditions provided by Article 30;²⁷⁹ namely that an exception a) must be

²⁷³ Sellin J (n 35) 193; UNCTAD-ICTSD (n 35) 430.

²⁷⁴ cf. TRIPS Agreement (n 32) Articles 27(2) and 27(3); Sellin J (n 35) 193.

²⁷⁵ Sellin J (n 35) 193.

²⁷⁶ The limitation to a brief overview, however, is appropriate for the focus of this research, as the author generally suggests that the importance of public health and the accessibility of medicines is of such magnitude that their protections should not merely constitute an exception to the general rule, as further elaborated in chapter 4.2.3.

²⁷⁷ TRIPS Agreement (n 32) Article 30.

²⁷⁸ Exceptions under Article 30 can be adopted for a variety of reasons, such as research purposes without commercial intent, experimentation even with commercial intent in order to invent around or improve a product, individual prescriptions of on-demand drugs directly made in a pharmacy, and early working, also known as the Bolar exception, allowing the production of a patented product for marketing approval purposes for generic drugs to enter the market once the patent expires. See thereto: UNCTAD-ICTSD (n 35) 437.

²⁷⁹ UNCTAD-ICTSD (n 35) 431; Sellin J (n 35) 193.

limited, b) must not unreasonably conflict with the normal exploitation of a patent, and c) must not unreasonably prejudice the legitimate interests of a patent owner, taking into account, however, the legitimate interests of third parties.²⁸⁰ In 2000, controversies regarding the legitimacy of exceptions provided under Article 30 TRIPS were addressed by a WTO panel in the *Canada – Patent Protection of Pharmaceutical Products* case.²⁸¹ The panel stated that for determining the justification of an exception, not only Article 30 TRIPS, but also the objectives and principles of Articles 7 and 8 have to be taken into consideration.²⁸² Furthermore, the panel identified that the exceptions provided by both Article 30 and Article 31 TRIPS are subject to the non-discrimination principle of Article 27(1), indicating, however, that discrimination and differential treatment are not the same, and that, in accordance with the Doha Declaration, the differential treatment of different fields of technology is not generally prohibited.²⁸³ The panel then held that legitimate exceptions are narrowly confined by the three conditions provided by Article 30, which, in the view of the panel, are cumulative, in that all three requirements must be fulfilled independently and separately from each other to justify an exception under Article 30.²⁸⁴

Firstly, an exception must be limited,²⁸⁵ i.e. subject to certain boundaries or confined within definite limits, for example regarding permissible acts, the purpose of use, eligible persons, or their duration.²⁸⁶ In this consideration, the panel in the *Canada – Patent Protection of Pharmaceutical Products* case held that the Bolar exception²⁸⁷ provided for by Canadian legislation, is not inconsistent with Article 30, as it is

²⁸⁰ TRIPS Agreement (n 32) Article 30.

²⁸¹ In the *Canada – Patent Protection of Pharmaceutical Products* case, the EC brought a complaint against Canada, which legislation provided two particularly controversial exceptions to pharmaceutical patent rights: 1) the Bolar exception, which allows the production of a patented product by a competitor in order to apply for marketing approval of a generic medication; and 2) a stockpiling exception, allowing the production and stockpiling of patented products by competitors up to six months prior the expiry of a patent, so that generic medicines can enter the market sooner after a patent expires. In the view of the EC, the exceptions provided by Canadian law were inconsistent with Articles 27(1) and 28(1) TRIPS. Canada, however, argued that while these measures impact the rights conferred by Articles 27(1) and 28(1), they constituted legitimate exceptions under Article 30 TRIPS. For a further discussion of the *Canada – Patent Protection of Pharmaceutical Products* case see: Gervais DJ, *The TRIPS Agreement* (n 129) paras 2.364ff; Sellin J (n 35) 196-198.

²⁸² cf. UNCTAD-ICTSD (n 35) 440.

²⁸³ *ibid* 442.

²⁸⁴ *ibid* 432-433.

²⁸⁵ TRIPS Agreement (n 32) Article 30.

²⁸⁶ UNCTAD-ICTSD (n 35) 433; Correa CM, *A commentary on the TRIPS Agreement* (n 129) 306-307.

²⁸⁷ See notes 278 and 281.

sufficiently limited regarding permissible acts and the purpose of use; i.e. the production of a patented product by a competitor, for the sole purpose of obtaining marketing approval.²⁸⁸ The stockpiling exception,²⁸⁹ however, was not considered to be sufficiently limited, in that the exception was for commercial purposes,²⁹⁰ and did not impose any limitation on the quantity of production.²⁹¹ The panel thus held that this exception unreasonably interfered with the right of a patent owner to prevent competitive commercial activities by others.²⁹²

Secondly, an exception shall not unreasonably conflict with the normal exploitation of a patent.²⁹³ As the TRIPS Agreement leaves this requirement undefined, the panel in the *Canada – Patent Protection of Pharmaceutical Products* case defined that the normal exploitation of a patent includes the right ‘to exclude all forms of competition that could detract significantly from the economic returns anticipated’ by a patent owner.²⁹⁴ A measure conflicting with the normal exploitation of a patent, however, may nevertheless be justified under Article 30, as long as the conflict is not unreasonable.²⁹⁵ As the term ‘unreasonable’ is not further defined, it can be suggested that the identification of the reasonableness of an exception should be conducted on a case by case basis, paying due regard to the objectives and principles of TRIPS, as reaffirmed by paragraph 5(a) of the Doha Declaration.²⁹⁶

Thirdly, an exception shall not unreasonably prejudice the legitimate interests of a patent owner, however, taking into account the legitimate interests of third parties.²⁹⁷ According to the WTO panel, legitimate interests are interests that are justified, i.e.

²⁸⁸ cf. Gervais DJ, *The TRIPS Agreement* (n 129) para 2.365; Sellin J (n 35) 197.

²⁸⁹ See note 281.

²⁹⁰ The stockpiling exception was regarded as being for commercial purposes as it facilitated the production and stockpiling of generic versions of patented products by competitors, with the purpose selling these products once a patent expired.

²⁹¹ WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products* (n 198) para 7.35; Gervais DJ, *The TRIPS Agreement* (n 129) para 2.365; Sellin J (n 35) 197-198.

²⁹² WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products* (n 198) para 7.35; Gervais DJ, *The TRIPS Agreement* (n 129) para 2.365; Sellin J (n 35) 197-198.

The narrow interpretation of the ‘limited’ requirement by the panel is not uncontroversial, and can be criticised for not putting enough emphasis on the objectives and principles of TRIPS, as the rejection of the stockpiling exception seems to disregard public health interests in the timely availability of cheaper generic drugs once a patent expires. See thereto: Sellin J (n 35) 197.

²⁹³ TRIPS Agreement (n 32) Article 30.

²⁹⁴ WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products* (n 198) para 7.55.

²⁹⁵ Sellin J (n 35) 198.

²⁹⁶ UNCTAD-ICTSD (n 35) 435.

²⁹⁷ TRIPS Agreement (n 32) Article 30.

supported by public policies and social norms.²⁹⁸ In this regard, and especially in consideration of the legitimate interests of third parties, it seems logical to suggest that legitimate interests are not limited to purely legal interests.²⁹⁹ While certain interpretative issues of Article 30 were clarified by the panel, some of the arguments of the EC and Canada raised new obscurities, for example regarding the term ‘third parties’, which were not further clarified by the panel.³⁰⁰ In particular, the EC argued that third parties under Article 30 encompass competitors only,³⁰¹ while Canada suggested that the interests of third parties include ‘general societal interests and particularly interests connected with health policy’.³⁰² In the absence of clarification by the panel, it is submitted by the author that in light of Articles 7 and 8 TRIPS, and the Doha Declaration, it seems sensible to follow Canada’s interpretation suggesting that the public interest constitutes a legitimate interest of third parties.

In conclusion, Article 30 TRIPS can provide distinct limitations for the exclusive rights granted to patent holders, intended to mitigate some of the detrimental effects patents may have.³⁰³ Particularly, the Bolar exception is of relevance for protecting public health, and for enhancing the accessibility of medicines, by enabling generic drugs to enter the market more rapidly after a patent expires.³⁰⁴ The narrow interpretation of the three requirements of Article 30, provided by the WTO panel, however, considerably limits the number of legitimate exceptions available for the protection of public health.³⁰⁵ Ultimately, it is therefore submitted that the narrow limitations of Article 30 constrain its capability to adequately protect public interests against the detrimental impacts of the exclusive patent rights provided by TRIPS.

²⁹⁸ WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products* (n 198) para 7.69.

²⁹⁹ Gervais DJ, *The TRIPS Agreement* (n 129) para 2.398ff.

³⁰⁰ Sellin J (n 35) 199.

³⁰¹ WTO Panel Report, *Canada – Patent Protection of Pharmaceutical Products* (n 198) para 7.62.

³⁰² *ibid* para 7.67.

³⁰³ cf. UNCTAD-ICTSD (n 35) 445.

³⁰⁴ cf. *ibid*.

³⁰⁵ Sellin J (n 35) 199-200.

2.4.3.7 Article 31: Other Use Without Authorization of the Right Holder

Article 31 TRIPS regulates exceptional uses of patented inventions other than those allowed under Article 30.³⁰⁶ In particular, Article 31 facilitates the granting of non-voluntary or compulsory licenses under specific circumstances, where the public interest is regarded of higher importance than the exclusive rights of patent owners.³⁰⁷ The concept of compulsory licensing is not new and existed in most nations long before the TRIPS Agreement was concluded.³⁰⁸ In brief, a compulsory license is granted by a government, directed at a single patented invention, permitting a third party to produce and use the patented goods without requiring the authorisation of the patent owner.³⁰⁹ However, compulsory licenses do not generally ‘break’ a patent, so that rights holders retain their exclusive rights towards all other actors interested in using the patented invention.³¹⁰ Thus, compulsory licenses are not intended to undermine the legitimate rights of patent holders, but to amend or regulate inappropriate market behaviour. The imposition of compulsory licenses can therefore, be utilised for the protection of public interests, by limiting the private power inherent to exclusive patent rights.³¹¹ In particular, such licenses can drive down prices, and facilitate follow-up and new inventions, thereby not only improving the affordability of products, but generally facilitating a wider accessibility.³¹²

In the context of addressing public health concerns, compulsory licenses can serve the purpose of reducing the prices of pharmaceutical products in order to make them accessible to a larger number of patients, including poorer members of the population.³¹³ India’s patent laws, for example, utilised this TRIPS flexibility for enhancing the accessibility of medicines, by implementing the non-availability of a pharmaceutical product at a ‘reasonably affordable price’ as a ground for issuing a

³⁰⁶ TRIPS Agreement (n 32) Footnote 7 to Article 31; cf. Sellin J (n 35) 201; UNCTAD-ICTSD (n 35) 461.

³⁰⁷ cf. Sellin J (n 35) 200; UNCTAD-ICTSD (n 35) 461.

³⁰⁸ UNCTAD-ICTSD (n 35) 462.

³⁰⁹ cf. Ho CM (n 31) 127; Sellin J (n 35) 200.

³¹⁰ Ho CM (n 31) 127.

³¹¹ cf. Sellin J (n 35) 200, UNCTAD-ICTSD (n 35) 461.

³¹² Correa CM, *A commentary on the TRIPS Agreement* (n 129) 313.

³¹³ Abbott FM and Reichman JH, ‘The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions’ (2007) 10 JIEL 921, 970.

compulsory license.³¹⁴ Furthermore, the general possibility of threatening the use of a compulsory license can provide an essential means of leverage for governments in negotiations with the industry, regarding the pricing of medicines.³¹⁵ Thereby, the availability of compulsory licenses is not only an exception to the exclusive rights granted by a patent, but also a means for ‘promoting effective price negotiations with patent holders’.³¹⁶

Article 31 TRIPS provides detailed conditions and limitations regulating the use of compulsory licenses, but refrains from defining or limiting the grounds upon which a compulsory license can be granted, indicating that WTO member states are free to self-determine these grounds.³¹⁷ Similarly, TRIPS does not limit the types of patents or products that can be subject to compulsory licensing.³¹⁸ The right of governments to freely determine the grounds upon which compulsory licenses can be granted was further reaffirmed by Article 5(b) of the Doha Declaration, which explicitly provides that every member of the WTO not only has the right to grant compulsory licenses, but also ‘the freedom to determine the grounds upon which such licenses are granted.’³¹⁹ Similarly, with regard to pharmaceutical products, TRIPS does not include any limitations on the types of diseases for which compulsory licenses can be granted.³²⁰ Again, this was reaffirmed by paragraph 1 of the Doha Declaration which, while mentioning examples of specific diseases, provides a non-exhaustive list of health conditions, thereby not limiting the applicability of the TRIPS flexibilities to any specific diseases.³²¹

It follows that compulsory licenses under TRIPS can theoretically be issued for any reasonable purposes.³²² In this respect, Article 31 simply regulates the procedures and conditions to be followed when issuing a compulsory license in order to ensure the

³¹⁴ Ho CM (n 31) 143.

³¹⁵ Abbott FM and Reichman JH (n 313) 970.

³¹⁶ *ibid.*

³¹⁷ cf. Correa CM, *A commentary on the TRIPS Agreement* (n 129) 313-314; Sellin J (n 35) 200; UNCTAD-ICTSD (n 35) 462.

³¹⁸ Ho CM (n 31) 127-129.

³¹⁹ Doha Declaration (n 64) Paragraph 5(b); cf. Reichman JH, ‘Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options’ (2009) *Pharmaceutical Regulations* 247, 249.

³²⁰ Outtersson K, ‘Disease-Based Limitations on Compulsory Licenses under Articles 31 and 31bis’ in Correa CM (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules: Intellectual Property in the WTO Volume I* (Edward Elgar Publishing 2010) 675.

³²¹ Doha Declaration (n 64) Paragraph 1.

³²² Gumbel M, ‘Is Article 31bis enough? The Need to Promote Economies of Scale in the International Compulsory Licensing System’ (2008) 22 *Temple Int’l & Comp. L. J.* 161, 167.

fairness of the system and its use in a legitimate manner.³²³ In general, compulsory licenses can be issued both for governmental use, and for use by third parties authorised by the government.³²⁴ Governments, however, cannot issue general compulsory licenses for entire fields of technology or types of enterprises, as, just like Article 30 TRIPS, Article 31 is subject to the non-discrimination principle of Article 27.1 regarding, inter alia, the field of technology.³²⁵

For the issuance of a compulsory license, Article 31(a) TRIPS provides that each ‘authorisation of such use shall be considered on its individual merits’.³²⁶ It follows that every application needs to be reviewed on a case-by-case basis to establish whether the criteria for the grant of a compulsory license are fulfilled.³²⁷ To protect the legitimate interests of patent owners, however, compulsory licenses should only be adopted as a measure of last resort. Thus, before a compulsory license can be granted, Article 31(b) requires that the proposed grantee has to engage in prior negotiations with the rights holder, seeking to obtain a voluntary license based on ‘reasonable commercial terms and conditions’.³²⁸ While this requirement is not further defined by TRIPS, ‘reasonable commercial terms and conditions’ seem to include the payment of adequate royalty fees, the reasonable duration of the license, and potential export restrictions to protect the interests of the patentee in other markets.³²⁹

The subsequent grant of a compulsory license is only adequate if such negotiations ‘have not been successful within a reasonable period of time.’³³⁰ The reasonableness of this period may, inter alia, depend on the purpose for which a license is required.³³¹ It can therefore be suggested that a license for the production of a life-saving drug would justify a relatively short negotiation period, as otherwise unwilling patent holders could abuse negotiations to substantially delay the issuance of compulsory licenses.³³² In this respect, Article 31(b) further provides that the requirement of prior negotiations can be waived in situations ‘of a national emergency or other

³²³ cf. UNCTAD-ICTSD (n 35) 462.

³²⁴ TRIPS Agreement (n 32) Article 31.

³²⁵ UNCTAD-ICTSD (n 35) 468 and 480.

³²⁶ TRIPS Agreement (n 32) Article 31(a).

³²⁷ cf. UNCTAD-ICTSD (n 35) 468; Gervais DJ, *The TRIPS Agreement* (n 129) para 2.409.

³²⁸ TRIPS Agreement (n 32) Article 31(b).

³²⁹ Gervais DJ, *The TRIPS Agreement* (n 129) para 2.409; UNCTAD-ICTSD (n 35) 469-470.

³³⁰ TRIPS Agreement (n 32) Article 31(b).

³³¹ UNCTAD-ICTSD (n 35) 470.

³³² *ibid.*

circumstances of extreme urgency or in cases of public non-commercial use.³³³ Of particular importance in this regard, is paragraph 5(c) of the Doha Declaration, acknowledging the right of each WTO member to self-determine what constitutes a national emergency or ‘other circumstances of extreme urgency’, further recognising that public health crises, including, but not limited to, HIV/AIDS, tuberculosis, malaria and other epidemics ‘can constitute a national emergency or other circumstance of extreme urgency.’³³⁴ To remedy anti-competitive behaviour, the requirement of prior negotiations can further be waived under Article 31(k) TRIPS, when a compulsory license is granted after a judicial review.³³⁵

According to Article 31(c) TRIPS, the scope and duration of a compulsory license ‘shall be limited to the purpose for which it was authorized’.³³⁶ As the TRIPS Agreement sets no criteria for the assessment of the scope and duration, it seems sensible to suggest that every compulsory license needs to be customised for the specific purpose of its authorisation.³³⁷ In consideration of this specific purpose, Article 31(g) TRIPS regulates that a compulsory license shall further be subject to termination once the circumstances that led to its authorisation cease to exist.³³⁸ Nevertheless, Article 31(g) acknowledges the importance of protecting the legitimate interests of the persons authorised under a compulsory license, to recover the potentially substantial investments made in order to work a compulsory license in the public interest.³³⁹ Without the safeguard provided by Article 31(g), it could be expected to be exponentially difficult to find a distributor willing to make such an investment.

To protect rights holders, Article 31 TRIPS provides certain safeguards to ensure that compulsory licenses do not unreasonably interfere with the legitimate interests of patent owners.³⁴⁰ In this respect, Article 31(h) requires the payment of adequate

³³³ TRIPS Agreement (n 32) Article 31(b).

³³⁴ Doha Declaration (n 64) Paragraph 5(c).

³³⁵ TRIPS Agreement (n 32) Article 31(k).

³³⁶ *ibid* Article 31(c).

³³⁷ Ho CM (n 31) 136-137.

³³⁸ TRIPS Agreement (n 32) Article 31(g).

³³⁹ *ibid*; UNCTAD-ICTSD (n 35) 474-475.

³⁴⁰ In addition to the here discussed paragraphs (h) and (f) of Article 31, the TRIPS Agreement provides further safeguards for the protection of patent owners in paragraphs (d), (e), (i), and (j), an analysis of which, however, exceeds the scope of this thesis. In essence, Article 31(d) and (e) TRIPS provide that compulsory licenses shall be non-exclusive and non-assignable. This non-exclusivity requirement allows patent holders to continue the commercialisation of their patented products, and to issue voluntary licenses to other manufacturers, while the non-assignability

remuneration to the rights holder, subject to the circumstances of each individual case.³⁴¹ To determine the adequacy of this remuneration, TRIPS provides that the ‘economic value of the authorization’ shall be taken into account.³⁴² While it would be in the interest of patent holders to receive a remuneration equivalent or similar to the market rate, it has to be borne in mind that compulsory licenses aim to serve higher public objectives, so that the term ‘adequate’ may suggest that the remuneration should rather be sufficient on a minimum level.³⁴³ In particular, in the context of the protection of public health, it can be suggested that remuneration for pharmaceutical products should be below the common market rate, to ensure that compulsory licenses can effectively reduce the prices of required medicines.³⁴⁴

Lastly, Article 31(f) TRIPS stipulates that compulsory licenses ‘shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use’,³⁴⁵ unless a compulsory license is issued in accordance with paragraph (k), to remedy anti-competitive behaviour.³⁴⁶ As the TRIPS Agreement does not provide any further guidance on the term ‘predominantly’, it is commonly suggested that the majority of products produced under a compulsory license, i.e. at least 50.1 percent, need to be produced for the supply of the domestic market.³⁴⁷ Simultaneously, this definition suggests that compulsory licenses can generally be issued for exportation, as long as the majority of products stay within the issuing country’s market.³⁴⁸ However, this also means that in situations where a product is urgently required abroad, production under a compulsory license can only be of assistance where the same product is required in the domestic market of the exporting country.

While the possibility to grant compulsory licenses should provide considerable benefits for enhancing the accessibility of medicines in developing countries, the

requirement aims to prevent the emergence of a market in compulsory licenses, which undermines the rights of patent holders. Furthermore, Article 31(i) and (j) TRIPS safeguard patent holders by granting them an opportunity to legally challenge both the initial decision to issue a compulsory license as well as any decisions concerning the remuneration provided to them under Article 31(h) TRIPS. See thereto: TRIPS Agreement (n 32) Article 31(d), (e), (i), and (j); Ho CM (n 31) 136; UNCTAD-ICTSD (n 35) 473.

³⁴¹ TRIPS Agreement (n 32) Article 31(h).

³⁴² *ibid.*

³⁴³ Ho CM (n 31) 138; UNCTAD-ICTSD (n 35) 475.

³⁴⁴ Ho CM (n 31) 138.

³⁴⁵ TRIPS Agreement (n 32) Article 31(f).

³⁴⁶ *ibid* Article 31(k).

³⁴⁷ cf. Correa CM, *A commentary on the TRIPS Agreement* (n 129) 321; Ho CM (n 31) 135; UNCTAD-ICTSD (n 35) 474.

³⁴⁸ UNCTAD-ICTSD (n 35) 474.

system provided by Article 31 was heavily criticised as being ineffective for a variety of reasons.³⁴⁹ In particular, it can be suggested that the WTO does not provide sufficient safeguards to prevent threats of trade sanctions against countries intending to utilise Article 31.³⁵⁰ A major problem in this respect, can be seen in the imbalance of power between developing countries and multinational corporations, particularly with regard to the pharmaceutical industry with exclusive rights over life-saving medications. Any government that intends or decides to grant a compulsory license does so in the knowledge that this will displease the patent holder, and that patent holders are likely to try anything to prevent a compulsory license being issued. This means that when the legal means to prevent such licenses under TRIPS are exhausted, a corporation might decide to retaliate against government decisions by withdrawing other patented products from markets where compulsory licenses are issued.³⁵¹ This happened for example, when Thailand issued a compulsory license for Abbott's HIV drug Kaletra. Abbott decided to withdraw from filing patents for seven new drugs in Thailand, including an HIV drug that is particularly suitable for Thailand's tropical climate.³⁵² Considering the severity of those threats, developing countries tend to be more cautious about issuing compulsory licenses, as the balance of power is lopsided towards the multinational industry.³⁵³

Similarly, developing countries and LDCs may be threatened by unilateral economic and/or trade sanctions imposed by industrialised nations.³⁵⁴ If a developed country government assumes that a compulsory license interferes with the interests of patent holding corporations based in their country, such a developed nation may try to intervene to prevent the issuing of such a license. One of the practices applied by developed country governments is to threaten trade sanctions, which may lead to even more severe problems in developing countries, than the acute health issues which the compulsory license is intended to alleviate.³⁵⁵ While this imposition of unilateral measures is not allowed under TRIPS and the WTO, trade sanctions are a very real

³⁴⁹ Sellin J (n 35) 210-211.

³⁵⁰ *ibid* 211.

³⁵¹ Ho CM (n 31) 149.

³⁵² *ibid* 150.

³⁵³ *ibid* 150-151.

³⁵⁴ *ibid* 151.

³⁵⁵ *ibid*.

threat for developing countries – as past state practices prove³⁵⁶ – and seem to be one of the main reasons for developing countries and LDCs refraining from issuing compulsory licenses.³⁵⁷

Additionally, compulsory licensing under TRIPS can be criticised for the complexity of the procedural and administrative requirements of Article 31 itself, which severely constrain the efficacy of the system.³⁵⁸ Scrutinising this inefficacy of the procedural requirements, it becomes apparent that a particular problem for the protection of public health is inherent in the requirement of prior negotiations with the rights holder. As the industry is not keen on providing licenses that lower their profitability, such negotiations are complicated and can become a rather lengthy process, thereby jeopardising the timely issuance of compulsory licenses for the protection of human health and life.³⁵⁹ Another obstacle to the efficacy of compulsory licenses is that such licenses seemingly only provide exceptions to patent rights under Section 5 of Part II TRIPS, not, however, to the data exclusivity provisions of Section 7 of Part II TRIPS,

³⁵⁶ A much-recited illustration of such unilateral threats can be found in the example of the United States pressurising Thailand as a countermeasure for making use of the flexibility to issue compulsory licenses for public health reasons. Thailand attempted to utilise the system provided by Article 31 to provide compulsory licenses for pharmaceuticals intended to treat cancer and heart diseases. This led to strong criticism from conservative media, pharmaceutical corporations, and industrialised country governments, which – disregarding the actual wording of TRIPS and the Doha Declaration – claimed that Thailand was in violation of global trade rules. For US retaliation measures, however, it is not necessary to be in violation of any specific TRIPS regulations. Thailand, although in compliance with international IP laws, was thus listed in the US ‘Special 301’ report for allegedly offering inadequate IP protection. As such a listing may have implications on the investment strategies of rights holding industries with severe impacts on the economy of a listed country, the action taken by the US governments must be regarded as an unjustified unilateral measure of economic pressure, leading to a reluctance of developing countries utilising compulsory licenses. See thereto: Boundsin A, ‘Thais warned over drug pricing pressure’ *Financial Times* (10 August 2007) <<https://www.ft.com/content/ad6e844a-46a5-11dc-a3be-0000779fd2ac>> accessed 14 Mai 2019; Ho CM (n 31) 151-152; Outtersson K (n 320) 673-675 and 678-682.

This practice of the United States is rather hypocritical, considering that when faced with their own health emergency, the US government was not hesitant to threaten the use of a compulsory license themselves. After the 9/11 attacks in 2001, when faced with potential biological warfare by anthrax infected mail, the United States decided to stockpile large amounts of the anthrax medication ciprofloxacin, and threatened the patent holder Bayer with the issuance of a compulsory license if Bayer was not willing to halve the price of the product. See thereto: Anderson B, ‘Better Access to Medicines: Why Countries are Getting “Tripped” up and Not Ratifying Article 31-Bis’ (2010) 1 Case W. Res. J.L. Tech. & Internet 165, 170; Dutfield G, ‘Delivering Drugs to the Poor: Will the TRIPS Amendment Help?’ 34 American Journal of Law & Medicine 107, 115-116; Reichman JH (n 319) 250.

³⁵⁷ Ho CM (n 31) 152.

³⁵⁸ Sellin J (n 35) 211.

³⁵⁹ cf. Dutfield G, ‘Delivering Drugs to the Poor’ (n 356) 120.

as discussed below in 2.4.4.³⁶⁰ If compulsory licenses did not include a right to waive these data exclusivity provisions, generic manufacturers would be required to conduct their own clinical trials, which would delay the introduction of generic medicines, and increase their costs.³⁶¹ Similarly, the requirement of adequate remuneration for the patent holder under Article 31(h) TRIPS, as discussed above, can have detrimental impacts on the pricing of generic medicines produced under compulsory licenses.

Most notably, however, the compulsory licensing system of TRIPS can be criticised for Article 31(f), as the export restriction seems to disregard the special needs of developing countries and LDCs in urgent need of cheaper generic medicines. While in theory, developing countries and LDCs can grant compulsory licenses for the production of generic drugs, in practice, most of those countries frequently lack the manufacturing capacity to do so.³⁶² While other countries that do have the required manufacturing capacity would potentially be willing to supply the required generic products, the export restriction of Article 31(f) provides a distinct legal obstacle.³⁶³ Developing countries without sufficient manufacturing capacity in the pharmaceutical sector cannot simply authorise an overseas manufacturer to work a compulsory license, as compulsory licenses need to be issued in the country of production as well.³⁶⁴ As the compulsory license in the manufacturing country would then be required to be predominantly for domestic use, that country would need to require the same generic medicine in order to grant a compulsory license, and could further only export a maximum of 49.9 percent of the production to the initial country in need.³⁶⁵ In this respect, the export restriction of Article 31(f) seems to unduly burden countries that rely on the importation of generic medicines to satisfy the health needs of their population.³⁶⁶ It was therefore recognised by the WTO General Council that the initial

³⁶⁰ This is indicated by the use of the term ‘other use of the subject matter of a patent’ in Article 31 TRIPS.

³⁶¹ Dutfield G, ‘Delivering Drugs to the Poor’ (n 356) 120.

³⁶² Reichman JH (n 319) 248.

³⁶³ *ibid*; Anderson B (n 356) 167.

Prior to the restrictions of TRIPS, developing countries that had developed manufacturing capacity in the pharmaceutical sector, such as India, were able to export generic drugs to other developing countries and LDCs. With the end of the transitional periods for developing countries in 2005, as elaborated below in 2.4.5, however, those countries are now required to comply with the export restriction of Article 31(f). See thereto: Abbott FM and Reichman JH (n 313) 934.

³⁶⁴ Dutfield G, ‘Delivering Drugs to the Poor’ (n 356) 121.

³⁶⁵ TRIPS Agreement (n 32) Article 31(f); cf. Dutfield G, ‘Delivering Drugs to the Poor’ (n 356) 121.

³⁶⁶ Anderson B (n 356) 171.

compulsory licensing system under Article 31 TRIPS was impractical for many countries, particularly for those that needed cheaper medications most urgently.³⁶⁷

This problem of WTO members with insufficient or no manufacturing capacity in the pharmaceutical sector was recognised by paragraph 6 of the Doha Declaration, which instructed the Council for TRIPS ‘to find an expeditious solution to this problem [...] before the end of 2002.’³⁶⁸ While not within the deadline, a solution was agreed upon on 30 August 2003, providing an interim waiver which then led to a permanent amendment to the TRIPS Agreement in January 2017, as elaborated in the next section.³⁶⁹

2.4.3.8 Article 31bis: The Initial Waiver and the TRIPS Amendment – Compulsory Licensing for Export Purposes

On 30 August 2003, after almost two years of negotiations, the WTO General Council adopted the Decision on the ‘Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health’, providing an interim waiver of the obligations under Article 31(f) TRIPS for exporting countries, allowing WTO members with pharmaceutical manufacturing capacity to produce medicines under compulsory licenses for export to countries without sufficient manufacturing capacity in need of such pharmaceuticals.³⁷⁰ Furthermore, this decision waives the requirement to pay remuneration to the rights holder under Article 31(h) for the importing member.³⁷¹ The system is designed to provide required medications to countries in need when a patent holder refuses to offer such medications ‘at a price or under conditions acceptable to the interested country.’³⁷² In this respect, the Chairperson of the General Council proclaimed that WTO members shall use the system in good faith for the protection of public health and not as ‘an instrument to pursue industrial or

³⁶⁷ *ibid* 172.

³⁶⁸ Doha Declaration (n 64) Paragraph 6.

³⁶⁹ WTO, WTO Doc WT/L/540 (n 89); WTO, WTO Doc WT/L/641 (n 91); See thereto: Abbas MZ and Riaz S, ‘Compulsory Licensing and Access to Medicines: TRIPS Amendment allows Export to Least-Developed Countries’ (2017) 12 *Journal of Intellectual Property Law & Practice*, 451, 451; Anderson B (n 356) 172; Correa CM, *A commentary on the TRIPS Agreement* (n 129) 325; Dutfield G, ‘Delivering Drugs to the Poor’ (n 356) 122; Ho CM (n 31) 198-209; UNCTAD-ICTSD (n 35) 474.

³⁷⁰ WTO, WTO Doc WT/L/540 (n 89); UNCTAD-ICTSD (n 35) 484.

³⁷¹ UNCTAD-ICTSD (n 35) 484.

³⁷² Correa CM, *A commentary on the TRIPS Agreement* (n 129) 339.

commercial policy objectives.³⁷³ This statement, however, does not generally prohibit corporations from acting for a commercial gain, as otherwise it would be extremely difficult to find private actors willing to work a compulsory license for the supply of countries in need.³⁷⁴ Ultimately, the statement simply indicates that the main intention of the system is the support of public health, and not the furthering of economic objectives.³⁷⁵

The initial waiver – as well as the now implemented Article 31*bis* – generally are applicable and necessary when three conditions are met:

- 1) A country needs more drugs at a lower price than currently obtainable,
- 2) that country has no or inadequate manufacturing capacity for the drugs in question, and
- 3) that country seeks to import cheaper generic drugs from a country willing to export such products.³⁷⁶

On 6 December 2005, WTO member states agreed to transform the interim waiver into the first permanent amendment to the TRIPS Agreement.³⁷⁷ After an initial deadline, which required the acceptance by two-thirds of the WTO members, was extended from 1 December 2007 to 31 December 2017, the TRIPS Amendment was eventually ratified and entered into force on 23 January 2017, implementing Article 31*bis* and an Annex to The TRIPS Agreement.³⁷⁸

Article 31*bis*(1) TRIPS provides that ‘[t]he obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s)’

³⁷³ WTO, ‘The General Council Chairperson’s Statement’ (30 August 2003) <https://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm> accessed 27 May 2019; cf. Abbott FM and Reichman JH (n 313) 945-946; UNCTAD-ICTSD (n 35) 485.

³⁷⁴ cf. UNCTAD-ICTSD (n 35) 485.

³⁷⁵ Abbott FM and Reichman JH (n 313) 946.

³⁷⁶ Ho CM (n 31) 201.

³⁷⁷ WTO, WTO Doc WT/L/641 (n 91); cf. Correa CM, *A commentary on the TRIPS Agreement* (n 129) 325; Yu PK, ‘The International Enclosure Movement’ (2007) 82 *Indiana Law Journal* 827, 881.

While Article 31*bis* is a measure intended to address situations that require urgent and timely intervention, paragraph 6 of the Annex to the TRIPS Agreement implicitly acknowledges that providing compulsory licenses for export purposes cannot be regarded as a sufficient long-term solution to the problems faced by many developing countries and LDCs. In this consideration, paragraph 6 recognises ‘the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector’ to overcome the problems faced by members without sufficient manufacturing capacity. See thereto: TRIPS Agreement (n 32) Annex, Paragraph 6.

³⁷⁸ cf. TRIPS Agreement (n 32); Abbas MZ and Riaz S (n 369) 451.

subject to the condition that this product is exported to an eligible³⁷⁹ importing Member.³⁸⁰ This waiver is further subject to a set of specific terms and conditions provided in paragraph 2 of the newly implemented Annex to the TRIPS Agreement.³⁸¹

Paragraph 2 of the Annex regulates the administrative and procedural conditions for the granting of compulsory licenses under the waiver system. According to Paragraph 2(a)(i), eligible importing members have to notify the Council for TRIPS about the ‘names and expected quantities of the product(s) needed’.³⁸² According to paragraph 2(a)(ii) of the Annex, the notification has to further confirm that an importing Member, other than a LDC, ‘has insufficient or no manufacturing capacities’ to produce the pharmaceutical product in question.³⁸³ Capacity in this regard has two dimensions; one being the technical capability, and the other being the economic feasibility.³⁸⁴ Article 31*bis* is no longer applicable once the manufacturing capacity in a formerly eligible importing member becomes sufficient to meet that country’s pharmaceutical

³⁷⁹ The ‘eligible importing member’ is defined by paragraph 1(b) of the Annex to the TRIPS Agreement as any LDC member, and any other country ‘that has made a notification to the Council for TRIPS of its intention to use the system set out in Article 31*bis* and this Annex (“system”) as an importer’. See: TRIPS Agreement (n 32) Annex, Paragraph 1(b). Furthermore, for the purpose of the waiver, Paragraph 1(a) of the Annex defines ‘pharmaceutical products’ as ‘any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognised by paragraph 1 of the’ Doha Declaration. It is further recognised that active ingredients necessary for the production of pharmaceutical products as well as diagnostic kits required for their use shall be included in this definition. While the waiver does not mention vaccinations, it can be suggested that if vaccines should be excluded, this would be explicitly mentioned. As vaccines, however, are ‘products of the pharmaceutical sector’, it seems logical to assume that they are included. Thus, the system is applicable to both product and process patents in the pharmaceutical sector, without limitation; i.e. the waiver is not limited to essential medications or specific diseases. While a limitation to ‘serious diseases’ was discussed in the drafting process of the waiver, ultimately, such a limitation was not adopted. See thereto: TRIPS Agreement (n 32) Annex, Paragraph 1(c); Correa CM, *A commentary on the TRIPS Agreement* (n 129) 326; Abbott FM and Reichman JH (n 313) 937; Ho CM (n 31) 204; Outtersson K (n 320) 681-682.

³⁸⁰ TRIPS Agreement (n 32) 31*bis*(1).

The wording of this provision, and particularly the reference to ‘the extent necessary’, indicates that the system shall only be applied under limited circumstances, which reflects the chairperson’s statement regarding use in good faith for the protection of public health. See thereto: Yu PK (n 377) 882.

³⁸¹ TRIPS Agreement (n 32) 31*bis*(1).

³⁸² *ibid* Annex, Paragraph 2(a)(i).

³⁸³ *ibid* Annex, Paragraph 2(a)(ii).

To be eligible as an importing member, countries other than LDCs need to show that they either have no manufacturing capacity in the pharmaceutical sector at all, or that they have no manufacturing capacity for the products in question, excluding any capacity owned by the patent holder. See thereto: TRIPS Agreement (n 32) Appendix to the Annex; Correa CM, *A commentary on the TRIPS Agreement* (n 129) 331.

³⁸⁴ Correa CM, *A commentary on the TRIPS Agreement* (n 129) 331.

production needs, at least in regard to the products in question.³⁸⁵ Lastly, under paragraph 2(a)(iii) of the Annex, the importing member has to confirm that where products are patented in its territory, ‘it has granted or intends to grant a compulsory license’ for such products.³⁸⁶

Paragraph 2(b) of the Annex then regulates the conditions an exporting country has to comply with, providing in paragraph 2(b)(i) that the exporting member shall only issue a compulsory license for ‘the amount necessary to meet the needs of the eligible importing Member(s)’, and that all products manufactured under the license shall be exported to that member.³⁸⁷ According to paragraph 2(b)(ii), ‘products produced under the license shall be clearly identified as being produced under the system through specific labelling or marking.’³⁸⁸ The rationale behind this regulation is to make such products easily identifiable in order to prevent their diversion into other markets.³⁸⁹ According to paragraph 2(b)(iii), information about the quantities of products shipped, as well as their distinguishing features shall then be published by the licensee on a website.³⁹⁰

Paragraph 2(c) of the Annex further requires the exporting member to notify the Council for TRIPS about the grant of a compulsory license, as well as the conditions attached to that license.³⁹¹ As the Annex simply serves the purpose of providing transparency when the system is used, there is no requirement for this notification to

³⁸⁵ TRIPS Agreement (n 32) Appendix to the Annex.

The assessment of the manufacturing capacity, however, is conducted by the importing country itself, and while the TRIPS Council needs to be notified, it cannot object to this assessment. See thereto: Ho CM (n 31) 202.

³⁸⁶ TRIPS Agreement (n 32) Annex, Paragraph 2(a)(iii).

³⁸⁷ TRIPS Agreement (n 32) Annex, Paragraph 2(b)(i).

The ‘needs’ are determined by the importing country alone, and the quantity ultimately required does not necessarily need to reflect the amount indicated in the initial notification. In consideration of the Chairpersons Statement, it should be clear that the quantities needed shall be determined in good faith. See thereto: Correa CM, *A commentary on the TRIPS Agreement* (n 129) 334.

³⁸⁸ TRIPS Agreement (n 32) Annex, Paragraph 2(b)(ii).

As the main purpose of the system is to make medications as cheap as possible, such distinction shall be feasible, and should not significantly impact the price of the product(s). See thereto:

TRIPS Agreement (n 32) Annex, Paragraph 2(b)(ii).

³⁸⁹ Correa CM, *A commentary on the TRIPS Agreement* (n 129) 334.

³⁹⁰ TRIPS Agreement (n 32) Annex, Paragraph 2(b)(iii).

³⁹¹ *ibid* Annex, Paragraph 2(c).

This notification shall include details of the licensee, the licensed products, the quantities, the country/countries that shall be supplied, the duration of the license, as well as the address of the website which the licensee publishes the information on. See thereto: TRIPS Agreement (n 32) Annex, Paragraph 2(c).

be approved by the WTO, meaning the Council for TRIPS cannot review or object to the notification, or its grounds and conditions.³⁹²

To avoid double remuneration payments, Article 31*bis*(2) TRIPS provides the importing country with a waiver of its obligation under Article 31(h) TRIPS, so that adequate remuneration to the patent holder shall only be paid in the exporting country, taking account, however, of the economic value to the importing member.³⁹³ Lacking a distinct definition of the adequacy standard for the remuneration, a controversy has arisen, with industrialised nations regularly arguing that adequate remuneration should provide full compensation to the patent holder, while developing countries suggest there should be no, or only a minimal compensation.³⁹⁴ The suggestion of no compensation fails to pay justice to the legitimate interests of patent holders.³⁹⁵ In respect to the public health objective of the Doha Declaration and the waiver, however, the author suggests that the remuneration should be low enough so as not to become an obstacle to the efficacy of the waiver, which aims to enhance the affordability of urgently required medicines.

While Article 31*bis*(1) and (2) waive the export restriction under Article 31(f), and the importing country's obligation under TRIPS to remunerate the patent holder under Article 31(h), the other requirements of Article 31 remain applicable.³⁹⁶ Article 31*bis*(5) clarifies that nothing in Article 31*bis*, nor in the Annex to the TRIPS Agreement, shall prejudice any of 'the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31' including those of the Doha Declaration and their interpretation.³⁹⁷ Among others, Article 31*bis* notably does not waive the requirement to seek a voluntary license from the patent owner under Article 31(b) TRIPS. The exporting

³⁹² Correa CM, *A commentary on the TRIPS Agreement* (n 129) 337; Gervais DJ, *The TRIPS Agreement* (n 129) para 2.412.

³⁹³ TRIPS Agreement (n 32) Article 31*bis*(2).

³⁹⁴ Anderson B (n 356) 176-177.

³⁹⁵ *ibid* 177.

³⁹⁶ *cf.* Correa CM, *A commentary on the TRIPS Agreement* (n 129) 332; Ho CM (n 31) 207.

³⁹⁷ TRIPS Agreement (n 32) Article 31*bis*(5).

Further, Article 31*bis* is 'without prejudice to the extent to which pharmaceutical products produced under' a regular compulsory license under Article 31(f) can be exported. See thereto: TRIPS Agreement (n 32) Article 31*bis*(5).

country may however rely on public non-commercial use or an emergency situation in the importing country to circumvent this requirement.³⁹⁸

To reduce the prices of generic medications, it is important to produce larger quantities in order to reduce the average unit cost. Addressing this so-called ‘economies of scale’, Article 31*bis*(3) TRIPS facilitates that under certain conditions generic pharmaceuticals under the waiver can be re-exported to other developing countries and LDCs within the area of a regional trade agreement, provided that the region consists of over 50% of LDCs.³⁹⁹ In all other circumstances, however, it is, according to paragraph 3 of the Annex, the obligation of eligible importing members to ‘take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system.’⁴⁰⁰ In addition, paragraph 4 of the Annex provides that all WTO members shall ensure that effective measures are available within their territories preventing the importation of re-exported products diverted into their markets.⁴⁰¹

Article 31*bis*(3) was rather controversially received, as the parameters within which countries can or cannot provide for economies of scale seem rather arbitrary.⁴⁰² The waiver depends on low prices to be effective, but commonly fails to offer the possibility of shipping sufficiently large quantities required to make low prices economical.⁴⁰³ Under Article 31*bis*(3) the realisation of economies of scale is generally permitted, subject, however, to three strict conditions. These conditions are that (1) countries utilising economies of scale need to be a party to a WTO recognised regional trade agreement (RTA), (2) at least half of the members of that RTA must be on the UN list of LDCs, and (3) the eligible importing country is responsible for the re-exportation of the medications to other eligible members within that RTA.⁴⁰⁴ The

³⁹⁸ Correa CM, *A commentary on the TRIPS Agreement* (n 129) 333; Abbott FM and Reichman JH (n 313) 940.

The patent owner, however, retains the rights under Article 31(i) and (j) to appeal the decision to grant a compulsory license and the amount of remuneration, which can turn into a lengthy process, delaying the distribution of the required medications. See thereto: Correa CM, *A commentary on the TRIPS Agreement* (n 129) 333; Ho CM (n 31) 208.

³⁹⁹ TRIPS Agreement (n 32) Article 31*bis*(3).

⁴⁰⁰ *ibid* Annex, Paragraph 3.

⁴⁰¹ *ibid* Annex, Paragraph 4.

⁴⁰² cf. Ho CM (n 31) 219.

⁴⁰³ *ibid*.

⁴⁰⁴ cf. TRIPS Agreement (n 32) Article 31*bis*(3); Gumbel M (n 322) 173.

imposed limitations in this provision create another burdensome process, leaving only a few countries eligible for facilitating economies of scale for making needed medications as affordable as possible.⁴⁰⁵ Furthermore, countries that do qualify under Article 31*bis*(3) TRIPS face additional administrative hurdles before they can make effective use of economies of scale.⁴⁰⁶ As the initial eligible importing country has to take the responsibility for administering the utilisation of the economies of scale, products produced under the waiver have to be first imported to this member, before they can be re-exported to other eligible countries that have the same public health problems.⁴⁰⁷ Ultimately, while the provisions set out by Article 31*bis* TRIPS are a step in the right direction, the current economies of scale provision does not provide the best way of making required drugs available at the cheapest possible price.⁴⁰⁸

Lastly, to provide a safeguard against lengthy and costly legal procedures under the WTO DSU, Article 31*bis*(4) TRIPS regulates that WTO members ‘shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994’.⁴⁰⁹ The rationale behind this regulation is to prevent non-violation nullification or impairment claims under GATT rules, as it is obvious that the use of compulsory licenses impairs the enjoyment of exclusive rights, which, under the conditions of Article 31*bis* and the Doha Declaration, is automatically justified.⁴¹⁰

The waiver system provided by Article 31*bis* TRIPS was repeatedly criticised by developing countries as ineffective, particularly concerning its inherent administrative hurdles and unnecessary obstacles.⁴¹¹ A strong indicator of the inefficacy of the system can be seen in the fact that as of 2018, the waiver has only been used once during its 15 years of existence, and that that use was hampered by several administrative

⁴⁰⁵ cf. Gumbel M (n 322) 177.

The economies of scale solution is severely restricted and basically only applies to Sub-Saharan Africa. Of the 30 RTAs currently listed on the WTO website, only six qualify for the economies of scale solution by fulfilling the requirement that at least 50% of their members are LDCs. This limitation is rather unnecessary and seems unjustified towards other LDCs, which similarly require economies of scale for making generic medicines as affordable as possible. See thereto: TRIPS Agreement (n 32) Article 31*bis*(3); Abbott FM and Reichman JH (n 313) 945; Gumbel M (n 322) 179.

⁴⁰⁶ cf. Gumbel M (n 322) 181.

⁴⁰⁷ cf. *ibid.*

⁴⁰⁸ *ibid* 182.

⁴⁰⁹ TRIPS Agreement (n 32) Article 31*bis*(4).

⁴¹⁰ cf. Abbott FM and Reichman JH (n 313) 945.

⁴¹¹ *ibid* 932; Anderson B (n 356) 173; Ho CM (n 31) 217.

difficulties.⁴¹² While some countries have reportedly considered using the waiver, they ultimately refrained due to the complexity of the requirements.⁴¹³ In this regard, Abbott and Reichmann argue that the cumbersome process ‘follows from the developed countries’ strategy of loading-up the Waiver Decision and Amendment with bureaucratic requirements.’⁴¹⁴ A further reason for the reluctance of developing countries to make use of the waiver is potentially connected to fears of political, economic, or trade repercussions – similar to those discussed above in 2.4.3.7 – which might follow once a country decides to use the system.⁴¹⁵ In this respect, particularly the requirement of public notifications about the intention to use the system, generates a risk of retaliatory sanctions.⁴¹⁶

In general terms, the complex and burdensome process under Article 31*bis* entails the likelihood of increasing costs and generating possibilities for delay.⁴¹⁷ An example can be seen in the requirement to establish that a developing country does not have adequate manufacturing capacities, which can be a rather costly process for most of those countries.⁴¹⁸ Further, the requirement that the generic manufacturer needs to enter into negotiations seeking a voluntary license from the patent holder is an additional burden with negative impacts on the timely availability of urgently required affordable medications.⁴¹⁹ Similarly, the required limitations of the duration and/or

⁴¹² cf. Abbas MZ and Riaz S (n 369) 452; Ho CM (n 31) 217.

In 2004, Médecins Sans Frontières (MSF) publicly committed to making use of the Canadian implementation of the export waiver, basically starting a first test run, providing valuable insights on how the system performs in practice. It took about half a year to find a pharmaceutical company (Apotex), willing to produce an HIV medication under the waiver, sold as Apo-TriAvir. The development of a generic copy took Apotex several months, and another six months were required for receiving marketing approval. As at that time, there was no developing country or LDC seeking the import of Apo-TriAvir, it took MSF and Apotex another year to find a country willing to use the waiver, which was eventually found in Rwanda. Apotex then had to enter a bidding process, in which the company faced competition from generic manufacturers in India, where the drug was not patented. To win the bid, Apotex agreed to sell Apo-TriAvir for \$0.195 per tablet; about half the price originally anticipated, which already was a ‘no profit’ price. After the final shipment under the compulsory license was made, there was still demand for the drug in Rwanda. To allow further shipments, however, Apotex would have needed to go through the whole cumbersome process again, but was not willing to do so anymore. The Canada/Rwanda experience thus evidences that the process provided by the waiver contains distinct problems and difficulties, aggravating its effective use. Ultimately, only the intervention by MSF and the willingness of Apotex to sell the drug without a profit ensured that the use of the waiver was semi-successful. See thereto: Anderson B (n 356) 180-181; Ho CM (n 31) 214-218.

⁴¹³ Ho CM (n 31) 217-218.

⁴¹⁴ Abbott FM and Reichman JH (n 313) 938.

⁴¹⁵ cf. *ibid*; Anderson B (n 356) 174.

⁴¹⁶ Anderson B (n 356) 175.

⁴¹⁷ *ibid* 174.

⁴¹⁸ Yu PK (n 377) 885.

⁴¹⁹ Abbas MZ and Riaz S (n 369) 452.

quantity for which a compulsory license can be granted constitute unnecessary hurdles which unreasonably interfere with the effectiveness of the waiver, as it is virtually impossible to accurately predict the course of public health crises.⁴²⁰ If any change of circumstances requires further shipments of generic drugs, the whole burdensome process has to be repeated.⁴²¹

While the system provided by Article 31*bis* is already intricate in itself, further complications may be introduced depending on how the national implementation of the waiver is conducted.⁴²² In general, before a compulsory license under the waiver can be granted, three basic requirements need to be fulfilled.⁴²³ First, an exporting country needs to implement laws facilitating the possibility of issuing compulsory licenses for export purposes. Second, a company willing to take up production under the waiver must be identified. And third, that company needs to receive a compulsory license.⁴²⁴ Accordingly, in most countries national patent laws need to be changed to enable the use of the system, as prior to the waiver, WTO members were required to implement an export restriction under Article 31(f) TRIPS.⁴²⁵ Furthermore, importing countries need to amend their laws to facilitate the issuance of compulsory licenses for import purposes, and to waive the remuneration requirement of Article 31(h) TRIPS.⁴²⁶ Such changes to domestic laws, however, may face legal difficulties in cases where countries have signed up to TRIPS-Plus agreements that restrict the use of the exceptions and flexibilities provided by TRIPS, as further discussed below in 2.5.1.4.⁴²⁷ As patent laws and regulatory laws operate separately from each other, it may be necessary for the importing country to make amendments to existing data exclusivity provisions⁴²⁸ in relation to the marketing approval of pharmaceuticals, in order to ensure that such regulations do not hinder the distribution of the licensed products.⁴²⁹ Similar amendments are required in the exporting country to ensure that

⁴²⁰ cf. *ibid.*

⁴²¹ *ibid.*

⁴²² Ho CM (n 31) 210.

⁴²³ *ibid.* 208.

⁴²⁴ cf. *ibid.*

⁴²⁵ Correa CM, *A commentary on the TRIPS Agreement* (n 129) 340.

⁴²⁶ Ho CM (n 31) 210.

⁴²⁷ cf. *ibid.* 209-210.

⁴²⁸ For the protection of undisclosed information and clinical test data under TRIPS, see below in 2.4.4.

⁴²⁹ Ho CM (n 31) 210.

data exclusivity provisions do not create barriers for the production of generic medications under compulsory licenses.⁴³⁰

A further considerable problem of the waiver is that its cumbersome regulations and requirements can make it rather complicated to find a generic manufacturer willing to produce under the system. One particular obstacle can be seen in the remuneration requirement. TRIPS does not provide any guideline on how the amount of remuneration should be determined, other than that the amount shall be adequate.⁴³¹ Therefore, the adequacy of remuneration payments will potentially be subject to intense debates and litigation.⁴³² The general lack of clarity regarding the remuneration may thus impact the decision making of generic manufacturers considering whether it is reasonable for them to make an investment in producing under a compulsory license.⁴³³ Furthermore, the production of generic pharmaceuticals under the waiver does not create distinct financial incentives, as only confined quantities at limited profit margins can be produced.⁴³⁴ Usually, generic manufacturers generate a return on their investments by selling large quantities at low prices.⁴³⁵ With the strict limitation of the production to the quantity needed by the eligible importer, potential producers might refrain from making necessary investments in required production facilities.⁴³⁶ At the same time, such constraints of the quantity seem to be required to protect the legitimate interests of patent holders.⁴³⁷ Nonetheless, it has to be borne in mind that generic manufacturers are not commonly charitable organisations, connoting that as players on the global market, their economic strategies are based on profitability considerations.⁴³⁸ Without a prospect of making sufficient profits, it may prove fairly difficult to find manufacturers willing to work under the waiver.

⁴³⁰ *ibid.*

⁴³¹ *ibid* 213.

⁴³² Gumbel M (n 322) 171.

⁴³³ Ho CM (n 31) 213-214.

⁴³⁴ *ibid* 217.

⁴³⁵ *ibid* 219.

⁴³⁶ Abbott FM and Reichman JH (n 313) 943.

⁴³⁷ *ibid.*

⁴³⁸ cf. Dutfield G, 'Delivering Drugs to the Poor' (n 356) 123.

2.4.4 Protection of Undisclosed Information under Part II Section 7 TRIPS

Besides patent rights, Part II of TRIPS regulates a second category of IP protection in Section 7, relevant to the context of public health and the accessibility of medicines. Formerly often referred to as trade secrets,⁴³⁹ Article 39 TRIPS is the first specific international provision addressing the protection of undisclosed information and test data.⁴⁴⁰ The use of the term ‘undisclosed information’ seems to be slightly misleading, as not all categories of undisclosed information are entirely undisclosed.⁴⁴¹ Of importance is rather that such information is not generally accessible to persons that commonly deal with that kind of information.⁴⁴² In this consideration, undisclosed information under Article 39 includes technical know-how, data of commercial value, and, of particular importance for the scope of this thesis, test or other data submitted for the marketing approval of pharmaceutical products.⁴⁴³ An important advantage for research based industries is, that unlike patents, the protection of undisclosed information is not subject to registration.⁴⁴⁴

According to Article 39(1) TRIPS, the protection of undisclosed information is aimed at ‘ensuring effective protection against unfair competition’.⁴⁴⁵ While the protection against unfair competition generally goes alongside industrial property rights – such as patents and trademarks – it commonly does not provide exclusive rights.⁴⁴⁶ This form of protection rather seems to provide redress against competitors who acquired secret information in an unlawful manner.⁴⁴⁷ Examples of this are provided in footnote 10 to Article 39(1) TRIPS, which enumerates ‘practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew,’ or should have known that unlawful practices were involved.⁴⁴⁸

⁴³⁹ UNCTAD-ICTSD (n 35) 520-521.

⁴⁴⁰ Sellin J (n 35) 213.

⁴⁴¹ Gervais DJ, *The TRIPS Agreement* (n 129) para 2.486.

⁴⁴² TRIPS Agreement (n 32) Article 39(2)(a).

⁴⁴³ UNCTAD-ICTSD (n 35) 521.

⁴⁴⁴ *ibid* 538.

⁴⁴⁵ TRIPS Agreement (n 32) Article 39(1).

⁴⁴⁶ UNCTAD-ICTSD (n 35) 521.

⁴⁴⁷ *ibid*.

⁴⁴⁸ TRIPS Agreement (n 32) Footnote 10 to Article 39(1).

In this consideration, the second paragraph of Article 39 stipulates that

[n]atural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices.⁴⁴⁹

Article 39(2) does not, however, protect the information itself, meaning that information which was lawfully acquired by competitors, for example by their own research, can be legally used by them.⁴⁵⁰ The protection of trade secrets under Article 39(2) TRIPS, and more importantly the general existence of such secrets, provides an indicative example of one of the main advantages of pharmaceutical patent rights; namely the disclosure of an invention for public use after a patent period expires.⁴⁵¹ This can be illustrated by reference to the history of Coca Cola. If the company had filed for a patent in 1886, the recipe would have been available for other manufacturers to copy from the early 20th century onwards. Coca Cola, however, decided against filing for a patent, rather keeping the recipe secret, thereby successfully protecting their invention for over 130 years now.⁴⁵² If this was done in the field of pharmaceuticals, the results would potentially be devastating. While without patent protection, competing corporations would be free to conduct their own research to come up with a generic version of a drug, this would require further lengthy and costly research processes and product safety trials. Consequently, the prices of such medicines would remain high, and research capacities would be missing for the development of other new medicines.

Article 39(3) TRIPS requires WTO member states to provide protection for test data and other data, submitted for the marketing approval of, inter alia, pharmaceutical products, against the disclosure of such information.⁴⁵³ The applicability of Article 39(3) is subject to four conditions, namely 1) that the submission of test data is required by a state ‘as a condition of approving the marketing of pharmaceutical or of agricultural chemical products’, 2) that such products ‘utilize new chemical entities’,

⁴⁴⁹ *ibid* Article 39(2).

⁴⁵⁰ UNCTAD-ICTSD (n 35) 527.

⁴⁵¹ TRIPS Agreement (n 32) Article 29.

⁴⁵² Olafson SE, ‘Patents vs. Trade Secrets – Giving Your Business the Competitive Edge’ (2007) 4(4) *Arizona BioInsider*, Special insert
<https://www.lrrc.com/files/Uploads/Documents/Olafson_AZBioInsider.pdf> accessed 22 May 2019.

⁴⁵³ TRIPS Agreement (n 32) Article 39(3).

3) that the generation of such data ‘involves a considerable effort’, and 4) that this information is otherwise undisclosed, i.e. not publicly available.⁴⁵⁴ As the scope of the term ‘new’ for the requirement of utilizing new chemical entities is not defined by the agreement, it is commonly suggested that this requirement is similar to the concept of novelty used for patents in Article 27 TRIPS,⁴⁵⁵ indicating that test or other data relating to new uses or new forms of known chemical compounds⁴⁵⁶ do not qualify for protection under Article 39(3).⁴⁵⁷

When the four requirements of Article 39(3) are fulfilled, WTO member states are obliged to provide protection for the data submitted against disclosure. Exceptions to this obligation are permissible where necessary for the protection of the public.⁴⁵⁸ In cases where such data is disclosed, however, steps have to be taken to protect this data against unfair commercial use,⁴⁵⁹ i.e. competition based on practices which are not equitable, not honest, not impartial, or not according to the rules.⁴⁶⁰

A question arising in this context is whether the protection of data submitted means that national authorities cannot rely on protected test data when examining the marketing approval application of an identical generic pharmaceutical product of a competitor.⁴⁶¹ If the protection of data submitted encompasses a period of exclusive use of that data, as provided for by some industrialised countries, it seems that national authorities must not rely on such data when considering the marketing approval of a generic product.⁴⁶² According to research-based industry, this is necessary for the protection of investments into clinical trials, and can further provide a certain degree of protection against generic competition in cases where patents have not been granted.⁴⁶³ If a period of exclusive use is not provided for by national legislation, competitors must still be prevented from using test data when such data was acquired in an unlawful manner.⁴⁶⁴ In the field of pharmaceuticals, however, a particular

⁴⁵⁴ *ibid* Article 39(3); cf. UNCTAD-ICTSD (n 35) 522.

⁴⁵⁵ cf. Gervais DJ, *The TRIPS Agreement* (n 129) para 2.487; UNCTAD-ICTSD (n 35) 530.

⁴⁵⁶ This is of particular importance in regard to TRIPS-Plus agreements, which frequently aim to introduce the patentability of such new uses, as further elaborated below in 2.5.1.1.

⁴⁵⁷ cf. Sellin J (n 35) 214; UNCTAD-ICTSD (n 35) 530.

⁴⁵⁸ TRIPS Agreement (n 32) Article 39(3).

⁴⁵⁹ *ibid*.

⁴⁶⁰ UNCTAD-ICTSD (n 35) 527.

⁴⁶¹ *ibid* 531.

⁴⁶² cf. *ibid*; Sellin J (n 35) 215.

⁴⁶³ Sellin J (n 35) 215.

⁴⁶⁴ UNCTAD-ICTSD (n 35) 531.

problem arises when a generic manufacturer is required to submit new test data, as this would necessitate new proceedings of tests – including animal and human trials – which is not only a waste of resources and research capacity, but also ethically questionable.⁴⁶⁵ In this context, some national courts have ruled that the reliance on prior submitted test data does not constitute ‘use’ of such data,⁴⁶⁶ and therefore cannot constitute unfair commercial use.⁴⁶⁷

Ultimately, the way Article 39 is implemented and applied can directly impact the accessibility of medicines, as an early availability of generic pharmaceuticals – which can only be guaranteed if the protection of undisclosed information does not prolong the process of marketing approval of such products – commonly reduces drug prices.⁴⁶⁸ While the TRIPS Agreement leaves considerable flexibility for the national implementation of Article 39, the associated research-based industry commonly strives to achieve a higher degree of protection. Therefore, as discussed below in 2.5.1.3, the protection of undisclosed information has become an important issue in TRIPS-Plus agreements, a number of which aim at limiting the flexibility provided by TRIPS.⁴⁶⁹

2.4.5 Transitional Arrangements under Part V TRIPS

Generally speaking, a transitional period is ‘the time period available for a WTO member to comply fully with the obligations set out by an Agreement’.⁴⁷⁰ All WTO member states had a general transitional period of one year, until 1 January 1996, from which date onwards all developed member states had to comply with the provisions set forth in the agreement.⁴⁷¹ Before TRIPS, many developing countries and least-developed countries (LDCs) did not have a comparable IP law system, so that the implementation of the agreement required, and in many cases still requires, substantial

⁴⁶⁵ cf. *ibid*; Sellin J (n 35) 216.

⁴⁶⁶ Test data is not *used* in the sense that for scrutinising the marketing approval application of a generic drug, it is commonly sufficient to establish bioequivalence of the generic product with the original product. See thereto: Hestermeyer H (n 54) 63.

⁴⁶⁷ cf. Hestermeyer H (n 54) 62-62; Gervais DJ, *The TRIPS Agreement* (n 129) para 2.488.

⁴⁶⁸ cf. Sellin J (n 35) 216; UNCTAD-ICTSD (n 35) 532.

⁴⁶⁹ cf. UNCTAD-ICTSD (n 35) 536.

⁴⁷⁰ Sellin J (n 35) 170.

⁴⁷¹ TRIPS Agreement (n 32) Article 65(1).

efforts.⁴⁷² In recognition of the challenges faced by developing countries, Articles 65 and 66 TRIPS introduced further transitional periods, applicable to developing countries and LDCs.⁴⁷³ These transitional periods, however, do not extend to Articles 3, 4, and 5 TRIPS,⁴⁷⁴ regulating the national treatment and most-favoured nation treatment, as addressed above in 2.2, as these principles are regarded as fundamental for the functioning of the TRIPS IP system.⁴⁷⁵ For all other provisions of the TRIPS Agreement, Article 65(2) granted developing countries a further four-year transition period until 1 January 2000.⁴⁷⁶ Furthermore, Article 65(4) TRIPS provided an additional five-year period, which ended on 1 January 2005, for developing countries to extend patent protection under Article 27 TRIPS to fields of technology that were formerly not patentable within their territory.⁴⁷⁷ This provision was particularly relevant for the protection of public health, as for many developing countries it provided an opportunity for delaying the implementation of pharmaceutical patent rights.⁴⁷⁸

In further recognition of the particular needs and requirements of LDCs, Article 66(1) TRIPS granted such countries a longer general transitional period of ten years.⁴⁷⁹ In accordance with paragraph 7 of the Doha Declaration, this transitional period was subject to several extensions by the WTO General Council, effectively extending the general transitional period until 1 July 2021.⁴⁸⁰ Additionally, the WTO General Council granted a further extension, until 1 January 2033, to the transitional period for

⁴⁷² Sellin J (n 35) 170.

⁴⁷³ TRIPS Agreement (n 32) Articles 65 and 66; cf. Sellin J (n 35) 170; UNCTAD-ICTSD (n 35) 706.

⁴⁷⁴ The transitional periods under TRIPS were subject to further limitations, regulated in Articles 65(5) and 70 TRIPS, preventing the roll back of protection once the patentability of products or processes was introduced to a new field of technology, and requiring the introduction of a so-called 'mail-box' system, facilitating patent applications before domestic patent laws extended to a particular field of technology. As, with the end of the transitional period for developing countries under Article 65 TRIPS in 2005, these limitations are not applicable anymore, they are of no further relevance for the scope of this thesis. See thereto: TRIPS Agreement (n 32) Articles 65(5) and 70; Sellin J (n 35) 172; UNCTAD-ICTSD (n 35) 715.

⁴⁷⁵ Sellin J (n 35) 171; UNCTAD-ICTSD (n 35) 713.

⁴⁷⁶ TRIPS Agreement (n 32) Article 65(2); cf. UNCTAD-ICTSD (n 35) 713.

⁴⁷⁷ TRIPS Agreement (n 32) Article 65(4).

⁴⁷⁸ UNCTAD-ICTSD (n 35) 714.

⁴⁷⁹ TRIPS Agreement (n 32) Art 66(1); UNCTAD-ICTSD (n 35) 715-716.

⁴⁸⁰ cf. Doha Declaration (n 64) Paragraph 7; WTO, 'Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products: Decision of the Council for TRIPS of 27 June 2002' (1 July 2002) WTO Doc IP/C/25; WTO, 'Extension of the Transition Period under Article 66.1 for Least Developed Country Members: Decision of the Council for TRIPS of 11 June 2013' (12 June 2013) WTO Doc IP/C/64.

LDCs with specific respect to the field of pharmaceuticals.⁴⁸¹ This extension exempts LDCs from the obligation to extend patent rights and the protection of undisclosed information to pharmaceutical products.⁴⁸² While this exemption should in theory be conducive to the protection of public health, in reality, the mere exclusion of pharmaceutical products from patentability in LDCs is not very effective.⁴⁸³ As discussed above in 2.4.3.7, LDCs commonly lack the manufacturing capacity to produce medicines themselves, so that they heavily depend on pharmaceutical imports.⁴⁸⁴ Consequently, it is the patent protection of pharmaceutical products in exporting countries, and the concomitantly higher drug prices, which constitutes the biggest threat to the availability of affordable medications in LDCs.

2.5 TRIPS-Plus Free Trade Agreements

The term ‘TRIPS-Plus’ is used to describe any IP law provision – commonly adopted in bilateral and multilateral⁴⁸⁵ free trade agreements (FTAs) – that implements higher levels of IP protection than required by the TRIPS Agreement, or provides limitations to the flexibilities of TRIPS.⁴⁸⁶ According to Article 1(1) TRIPS, as discussed above in 2.4.2.1, WTO members are required to implement at least the minimum IP protection standards provided by TRIPS into their domestic laws.⁴⁸⁷ This connotes that countries are free to negotiate and adopt higher standards of IP protection, not, however, lower.⁴⁸⁸ Furthermore, the TRIPS Agreement left many terms and provisions

⁴⁸¹ WTO, ‘Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products: Decision of the Council for TRIPS of 6 November 2015’ (6 November 2015) WTO Doc IP/C/73, para 1.

⁴⁸² *ibid* para 1.

⁴⁸³ Sellin J (n 35) 173.

⁴⁸⁴ *ibid*.

⁴⁸⁵ Multilateral trade agreements, sometimes referred to as plurilateral agreements, are concluded between some, but not all WTO member states. For the purpose of this thesis, the use of the term multilateral in regard to TRIPS-Plus agreements shall be synonymous to the WTO jargon of plurilateral. Agreements encompassing all members of the WTO will be referred to as international or global agreements. See thereto: Atik J, ‘ACTA and the Destabilization of TRIPS’ (2011). Loyola-LA Legal Studies Paper No. 2011-18, as published on SSRN <<https://ssrn.com/abstract=1856285>> accessed 27 May 2019, 6-7.

⁴⁸⁶ Bernieri RC, ‘Compulsory Licensing and Public Health: TRIPS-Plus Standards in Investment Agreements’ (2009) as published on SSRN <<https://ssrn.com/abstract=2101574>> accessed 21 October 2017, 14-15; Ho CM (n 31) 225.

⁴⁸⁷ TRIPS Agreement (n 32) Article 1(1).

⁴⁸⁸ cf. Sell SK, ‘TRIPS-Plus Free Trade Agreements and Access to Medicines’ (2007) 28 *Liverpool Law Review* 41, 59.

without distinct definitions, allowing flexibilities for domestic interpretation by WTO members. TRIPS-Plus provisions in FTAs utilise this freedom granted by TRIPS, and adopt IP protection that goes beyond the minimum standards.⁴⁸⁹ TRIPS-Plus FTAs can further provide clear definitions for the terms left open by TRIPS, thereby limiting the flexibility of governments to interpret the provisions in a way best suited to their own needs.⁴⁹⁰

In the belief that the TRIPS Agreement would adequately reflect the interests of industrialised nations, some developing countries expected the minimum standards to simultaneously be the limits of international IP protection, therefore assuming that unilateral pressure by developed countries would discontinue.⁴⁹¹ However, it became apparent that TRIPS only constitutes the base for a further push for extended protection, driven by developed countries.⁴⁹² Having failed to achieve the desired level of IP protection in TRIPS, industrialised nations began shortly after the agreement's conclusion with the negotiation of higher IP standards, including more extensive protection, new areas of IP rights, and the attenuation of flexibilities and the special treatment of developing countries.⁴⁹³

It seems that the reasons for developing countries to agree to higher levels of IP protection are the same for TRIPS-Plus FTAs as they were for the TRIPS Agreement.⁴⁹⁴ While TRIPS-Plus protection can be implemented by any country on its own, more commonly higher protection standards are adopted as a result of international negotiations and external pressure.⁴⁹⁵ In theory, sovereign governments are free to agree to or reject FTAs, or specific regulations thereof, throughout the negotiations. In practice, however, there is an imbalance of power between the

⁴⁸⁹ Frankel S, 'Challenging TRIPS-Plus Agreements: The Potential Utility of Non-Violation Disputes' (2009) 12 JIEL 1023, 1025.

⁴⁹⁰ cf. Ho CM (n 31) 225; Lopert R and Gleeson D, 'The High Price of "Free" Trade: U.S. Trade Agreements and Access to Medicines' (2013) 41 J Law Med Ethics 199, 200.

⁴⁹¹ Frankel S (n 489) 1041; Ho CM (n 31) 227; Mercurio B, 'TRIPS-Plus Provisions in FTAs: Recent Trends' in Bartels L and Ortino F (eds), *Regional Trade Agreements and the WTO Legal System* (OUP 2006) 215-216; Sell SK (n 488) 58-59.

⁴⁹² Frankel S (n 489) 1029; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 215-216.

⁴⁹³ Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 215 and 219; Lopert R and Gleeson D (n 490) 199; Sell SK (n 488) 59.

⁴⁹⁴ Bernieri RC, 'Intellectual Property Rights in Bilateral Investment Treaties and Access to Medicines: The Case of Latin America' (2006) 9 JWIP 548, 552.

⁴⁹⁵ Ho CM (n 31) 226.

negotiating parties, and developing countries tend to accept unfavourable IP standards as a trade-off for potential gains in other areas of trade.⁴⁹⁶

Exploiting this imbalance of power, developed countries⁴⁹⁷ can achieve their goals by applying economic pressure, for example by threatening the withdrawal of trade preferences or the imposition of sanctions, or by offering trade-offs such as market access in exchange for higher IP protection.⁴⁹⁸ This strategy has been adopted in both TRIPS and TRIPS-Plus negotiations, particularly because developing countries with an up-striving export industry are prone to submitting to trade-offs for gaining wealthy export markets.⁴⁹⁹ As part of these trade-offs, governments may further accept restrictions to the accessibility of medicines today, in the belief that profit maximisation for the industry is a necessary compromise to ensure that future advances in the medical field lead to benefits for the public interest.⁵⁰⁰

In this regard, particularly the research-based pharmaceutical industry pushed for higher protection as it considered TRIPS to be insufficient.⁵⁰¹ In 2004, Pharmaceutical Research and Manufacturers of America (PhRMA) questioned the value of the WTO, explicitly stating that the Doha Declaration – and thereby the protection of public health – constituted an obstacle to achieving higher international IP protection.⁵⁰² As the WTO thus has increasingly become an unfavourable forum for extending IP protection,⁵⁰³ PhRMA successfully lobbied the US government to strategically use FTAs to gradually ‘ratchet up’ international IP standards beyond the requirements of TRIPS.⁵⁰⁴ To this end, developed countries shifted negotiations for higher IP

⁴⁹⁶ Frankel S (n 489) 1025 and 1040; Ho CM (n 31) 226; Morin JF, ‘Tripping up TRIPS Debates IP and Health in Bilateral Agreements’ (2006) 1 *Int. J. Intellectual Property Management* 37, 37.

⁴⁹⁷ Particularly the US and the EU have adopted such measures pressuring developing countries to accept higher levels of IP than required by TRIPS. See thereto: Townsend B, Gleeson D, and Lopert R, ‘The Regional Comprehensive Economic Partnership, Intellectual Property Protection, and Access to Medicines’ (2016) *Asia Pacific Journal of Public Health* 682, 683.

⁴⁹⁸ cf. Bernieri RC, ‘Intellectual Property Rights in Bilateral Investment Treaties’ (n 494) 552; Ho CM (n 31) 226; Townsend B, Gleeson D, and Lopert R (n 497) 683.

⁴⁹⁹ Ho CM (n 31) 226-227; Lopert R and Gleeson D (n 490) 201; Morin JF (n 496) 38.

It has sometimes been suggested that developing countries are willing to enter into bilateral and regional TRIPS-Plus FTAs with the expectation of being in a better position when competing with other developing countries. See thereto: Bernieri RC, ‘Intellectual Property Rights in Bilateral Investment Treaties’ (n 494) 560.

⁵⁰⁰ Lopert R and Gleeson D (n 490) 218.

⁵⁰¹ *ibid* 199; Ho CM (n 31) 227.

⁵⁰² Morin JF (n 496) 40.

⁵⁰³ cf. Abbott FM and Reichman JH (n 313) 962; Atik J (n 485) 4.

⁵⁰⁴ Abbott FM and Reichman JH (n 313) 962; Lopert R and Gleeson D (n 490) 199 and 210; Morin JF (n 496) 40.

protection from the international forum under the WTO and WIPO to the bilateral and multilateral level in order to undermine the combined resistance of the developing world, by isolating developing countries from stronger coalitions, and limiting NGO support, in smaller scale FTAs.⁵⁰⁵

Compared to the WTO level, negotiations with a smaller number of developing countries offer a higher chance for TRIPS-Plus IP standards being accepted, so that FTAs are liable to enable industrialised countries to circumvent WTO measures aimed at the protection of public health.⁵⁰⁶ Furthermore, it seems that IP policy is generally directed towards a constant proliferation of private rights, with TRIPS-Plus FTAs following a sentiment that considers private investment protection of higher importance than the broader public interest.⁵⁰⁷ Consequently, each new FTA seemingly intends to implement higher standards of IP protection, introducing further regulations that delay the availability of generic medicines, and limit the TRIPS flexibilities designed to safeguard public health.⁵⁰⁸

In acknowledgement of the potentially detrimental impacts of certain TRIPS-Plus provisions, some FTAs include side letters, i.e. ancillary documents to a contract or treaty, providing that the regulations of an agreement shall not restrict the ability of governments to take measures for the protection of public health.⁵⁰⁹ While such side letters, as commonly advocated by developing countries, seem to pay due regard to public health concerns and the flexibilities provided by the Doha Declaration, they raise many questions about their significance.⁵¹⁰ As public health is commonly only addressed in preambles and side letters, rather than in the main text of FTAs, there exists an uncertainty about the interpretational value and binding nature of such statements.⁵¹¹

⁵⁰⁵ Atik J (n 485) 5; Lopert R and Gleeson D (n 490) 201; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 215 and 219-220; Morin JF (n 496) 38-40.

⁵⁰⁶ Ho CM (n 31) 227; Morin JF (n 496) 38.

⁵⁰⁷ Bernieri RC, 'Compulsory Licensing and Public Health' (n 486) 15; Bernieri RC, 'Intellectual Property Rights in Bilateral Investment Treaties' (n 494) 556; Grosse Ruse-Khan H, 'The International Law Relation between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities?' (2011) 18 J Intell. Prop. L. 325, 328-329; Lopert R and Gleeson D (n 490) 201.

⁵⁰⁸ Ho CM (n 31) 251; Lopert R and Gleeson D (n 490) 201; Grosse Ruse-Khan H (n 507) 327-328.

⁵⁰⁹ Ho CM (n 31) 250; Bernieri RC, 'Compulsory Licensing and Public Health' (n 486) 20; Xiong P, 'Patents in TRIPS-Plus Provisions and the Approaches to Interpretation of Free Trade Agreements and TRIPS: Do They Affect Public Health?' (2012) 46 Journal of World Trade 155, 183-184.

⁵¹⁰ Bernieri RC, 'Compulsory Licensing and Public Health' (n 486) 20.

⁵¹¹ Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 234.

2.5.1 An Overview of Reoccurring TRIPS-Plus Standards

As indicated above, TRIPS-Plus provisions in FTAs frequently introduce new or more strictly defined criteria for patentability, thereby limiting the flexibilities provided by TRIPS, taking away the opportunity for developing countries to implement the agreement in a way most suitable to their specific individual requirements. TRIPS-Plus FTAs typically allow for the patentability of a broader scope of inventions, for example by exploiting the fact that TRIPS does not define the terms ‘new’, ‘useful’ or ‘capability of industrial application’, and ‘inventive step’.⁵¹² As countries can voluntarily implement higher standards of protection than required by TRIPS, TRIPS-Plus agreements can further be used to limit the special treatment granted to LDCs, requiring them to provide patent protection for pharmaceuticals before the end of the transitional periods.⁵¹³

The following section provides a general overview of frequently reoccurring TRIPS-Plus provisions that have been particularly criticised for their adverse impacts on public health and the accessibility of medicines.⁵¹⁴ This overview is only indicative, and cannot address all types of TRIPS-Plus provisions due to the constraints of this thesis. The focus of the next section therefore lies on measures extending the scope of patentability, extensions to patent terms, extended data exclusivity rights, restrictions of exceptions, exacerbations of the use of compulsory licenses, and the linking of patents to regulatory approval.⁵¹⁵ Measures not further addressed by this thesis include, inter alia, regulations for goods in transit,⁵¹⁶ restrictions of pre-grant

⁵¹² Ho CM (n 31) 232.

⁵¹³ cf. Townsend B, Gleeson D, and Lopert R (n 497) 689.

⁵¹⁴ Bernieri RC, ‘Compulsory Licensing and Public Health’ (n 486) 3.

⁵¹⁵ cf. Abbott FM and Reichman JH (n 313) 963; Bernieri RC, ‘Compulsory Licensing and Public Health’ (n 486) 3; Townsend B, Gleeson D, and Lopert R (n 497) 683.

⁵¹⁶ For further information on TRIPS-Plus regulations on goods in transit see: Abbott FM and Reichman JH (n 313) 966; Mercurio B, ‘Seizing’ Pharmaceuticals in Transit: Analysing the WTO Dispute that Wasn’t (2012) 61 *International and Comparative Law Quarterly* 389; Townsend B, Gleeson D, and Lopert R (n 497) 687.

opposition,⁵¹⁷ restrictions of international exhaustion,⁵¹⁸ and restrictions of price controls.⁵¹⁹

2.5.1.1 Extended Scope of Patentability: New Uses and 'Patent Evergreening'

While TRIPS requires inventions to be new in order to be patentable, WTO members are free to determine what exactly the term 'new' encompasses.⁵²⁰ To broaden the scope of patentability, FTAs regularly provide clear definitions of what is considered new, thereby limiting the right of governments to self-determine this requirement under domestic law.⁵²¹ TRIPS-Plus agreements regularly provide that new forms and new uses or new methods of using known substances shall satisfy the premise of being new, requiring the patentability of new uses even when they do not lead to improved efficacy.⁵²² As this was not required by the TRIPS Agreement, most developing

⁵¹⁷ For further information on TRIPS-Plus restrictions of pre-grant opposition see: Ho CM (n 31) 234-235.

⁵¹⁸ For further information on TRIPS-Plus restrictions of international exhaustion see: Ho CM (n 31) 240; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 233.

Because of the limitations of this thesis, restrictions of international exhaustion are excluded from this chapter, as this overview of TRIPS-Plus standards predominantly focusses on their detrimental impacts. Restrictions of international exhaustion, however, should not necessarily be regarded as detrimental. While these restrictions prevent countries from importing drugs from markets where medicines may be available at cheaper prices, the prevention of international exhaustion may also incentivise patent holders to adopt a differential pricing strategy. Differential pricing strategies facilitates that medicines are offered at cheaper prices in low-income countries, under the premise that these products are not re-exported to wealthy markets, as elaborated in further detail in chapter 5.2.2.4.

⁵¹⁹ While restrictions of price control measures can directly affect the pricing of pharmaceuticals, for the affordability of medicines in developing countries such measures are of comparatively little importance. As price control measures are generally further subject to negotiations with distributor companies, they are commonly most effective when applied by public healthcare providers of industrialised countries with wealthy markets, where a certain degree of power balance exists between distributor and purchaser, facilitating adequate negotiations. In this consideration it can be suggested that developing countries have considerably less power to effectively employ such strategies. For further information on TRIPS-Plus restrictions of price controls see: Ho CM (n 31) 246-248; Lopert R and Gleeson D (n 490) 204-206; US Department of Commerce – International Trade Administration, '2016 Top Markets Report Pharmaceuticals Country Case Study: South Korea' (2016) <https://www.trade.gov/topmarkets/pdf/Pharmaceuticals_Korea.pdf> accessed 27 May 2019.

⁵²⁰ cf. Ho CM (n 31) 225 and 232; Morin JF (n 496) 41.

⁵²¹ cf. Ho CM (n 31) 225 and 233.

⁵²² *ibid*; Kilic B, Brennan H, and Maybarduk P, 'What Is Patentable Under the Trans-Pacific Partnership? - An Analysis of the Free Trade Agreement's Patentability Provisions from a Public Health Perspective' (2015) 40 Yale Journal of International Law Online 1, 6 <<http://www.yjil.org/docs/pub/o-40-killic.pdf>> accessed 27 May 2019; Lopert R and Gleeson D (n 490) 207; Mitchell A, Voon T, and Whittle D, 'Public Health and the Trans-Pacific Partnership Agreement' (2015) 5 Asian Journal of International Law 279, 301; Morin JF (n 496) 41; Stuhldreier M (n 119) 183; Townsend B, Gleeson D, and Lopert R (n 497) 686.

countries did not facilitate the patentability of new uses prior to TRIPS-Plus, and some countries, like India for example, explicitly preclude the patentability of new forms and new uses of known substances.⁵²³

The patentability of new forms and uses of known products basically eliminates the requirement of an inventive step, thereby abrogating the purpose of patents to provide incentives for true innovation.⁵²⁴ This further creates an opportunity for rights holders to utilise new use patentability in order to extend monopoly positions for older pharmaceuticals, preventing generic medicines from entering the market once the initial patent period expires.⁵²⁵ This facilitates the possibility of ‘patent evergreening’, a business strategy that can not only extensively delay the market entry of generic medicines, but likewise can delay the availability of new or improved treatment methods when the disclosure of knowledge is postponed for strategic purposes.⁵²⁶ To utilise the evergreening of a patent, the rights holder can apply strategic methods to effectively manage the life-cycle of the patent by withholding certain knowledge and data when filing for an initial patent application. Towards the end of the first patent period, the patent holder can then disclose the formerly withheld information to establish new uses, new target groups, or new methods of administering a medical product in order to receive a successive patent, extending the product’s monopoly position.⁵²⁷

The adverse consequences of patent evergreening can be illustrated with the aid of a hypothetical example of the well-known drug Aspirin, a multi-purpose drug probably best known for its use as a mild pain killer. However, Aspirin is further used for the treatment of stroke and heart attack patients, and for the treatment of colorectal cancer.⁵²⁸ For this theoretical example it shall be presupposed that Aspirin currently was a novel drug and that all its uses are known to its inventor. To utilise the strategy of patent evergreening, the originator company can file for an initial patent for Aspirin as a mild painkiller. Delaying the disclosure of information on Aspirin’s capabilities

⁵²³ Townsend B, Gleeson D, and Lopert R (n 497) 686.

⁵²⁴ Stuhldreier M (n 119) 184.

⁵²⁵ *ibid* 183; Ho CM (n 31) 234; Kilic B, Brennan H, and Maybarduk P (n 522) 4-5.

⁵²⁶ Lopert R and Gleeson D (n 490) 201; Stuhldreier M (n 119) 184-185; Townsend B, Gleeson D, and Lopert R (n 497) 686.

⁵²⁷ Stuhldreier M (n 119) 183-185.

⁵²⁸ *cf.* *ibid* 180; Nordqvist C, ‘Uses, Benefits, and Risks of Aspirin’ (last updated 18 December 2017) <<http://www.medicalnewstoday.com/articles/161255.php>> accessed 27 May 2019.

for the treatment of strokes and heart attacks to the end of the first 20-year patent period, enables the company to acquire a second patent, extending the monopoly position by another 20 years. This process can then be repeated, providing a third patent period for the treatment of colorectal cancer. At this stage, Aspirin has an effective patent term of 60 years, with the patentability of new uses delaying the market entry of cheaper generic versions by 40 years. This strategy further delays the availability of Aspirin as a medication for strokes and heart attacks by 20 years, and for colorectal cancer by 40 years, leaving patients without treatment for purely monetary reasons.⁵²⁹

While it may be argued that the patentability of new uses creates research incentives for finding improved treatment uses of known substances, it can be suggested that the detrimental effects to public health caused by patent evergreening outweigh its benefits. This can be supported by the fact that Aspirin was first invented well before the patentability of new uses existed, and that further uses were discovered even without the incentive of successive patent protection.⁵³⁰

2.5.1.2 Patent Term Extensions: Effective Protection Periods

According to Article 33 TRIPS, the 20-year minimum patent term is counted from the date a patent application is filed.⁵³¹ The time required for the examination of patent applications therefore reduces the effective protection period.⁵³² For pharmaceutical products, the marketable patent term is further curtailed as pharmaceutical patents are of no commercial value before a drug has received marketing approval, which usually takes between eight to twelve years.⁵³³ To compensate for such administrative delays, many FTAs include regulations that require members to provide patent term extensions at least for unreasonable delays in either of the approval processes.⁵³⁴ These patent term extensions particularly tend to prolong patent periods in developing

⁵²⁹ cf. Stuhldreier M (n 119) 180 and 185.

⁵³⁰ For a brief overview of the historic development of Aspirin, see: Roberts L, 'Aspirin Timeline' *The Telegraph* (07 December 2010) <<https://www.telegraph.co.uk/news/health/news/8185164/Aspirin-timeline.html>> accessed 27 May 2019.

⁵³¹ Ho CM (n 31) 235.

⁵³² *ibid*; Morin JF (n 496) 43.

⁵³³ Ho CM (n 31) 236; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 229; Morin JF (n 496) 43.

⁵³⁴ Ho CM (n 31) 236; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 229; Morin JF (n 496) 43; Stuhldreier M (n 119) 186.

countries, as patent offices and regulatory approval authorities in developing countries frequently lack sufficient expertise for dealing expeditiously with applications.⁵³⁵

While patent term extensions for unreasonable delays seem justified from an economic perspective, they also delay the introduction of generic medicines.⁵³⁶ This can have considerable impact on the timely availability of affordable generic drugs in developing countries, aggravating public health concerns already faced by these countries.⁵³⁷ Ultimately, while patent term extensions seem to be a just compensation for the industry, they mainly burden patients in need of treatment who cannot afford higher priced patented products.⁵³⁸ It is therefore submitted that such extensions are inappropriate for dealing with unreasonable delays, and that instead measures should be developed to improve the efficiency of the review processes to limit the occurrence of unreasonable delays in the first place.⁵³⁹

2.5.1.3 Extended Data Exclusivity Provisions

Under Article 39 TRIPS, WTO members are only required to protect the data submitted for regulatory approval from unfair commercial use, which, as discussed above in 2.4.4, potentially does not exclude generic manufacturers from relying on clinical test data originally submitted by the rights holder.⁵⁴⁰ As Article 39 TRIPS further does not require a specified period of data protection, WTO members are generally free to grant marketing approval for generic medicines based on test data submitted by a prior patent owner.⁵⁴¹ This provides a cost effective way for ensuring the timely market entry of generic drugs, because in order to receive marketing approval a generic manufacturer is simply required to establish that the generic drug is identical to a prior approved medicine.⁵⁴²

⁵³⁵ Ho CM (n 31) 237.

⁵³⁶ Lopert R and Gleeson D (n 490) 201; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 230; Stuhldreier M (n 119) 186; Townsend B, Gleeson D, and Lopert R (n 497) 686.

⁵³⁷ Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 230.

⁵³⁸ Stuhldreier M (n 119) 187.

⁵³⁹ *ibid.*

⁵⁴⁰ Ho CM (n 31) 241.

⁵⁴¹ Lopert R and Gleeson D (n 490) 200; Bernieri RC, 'Intellectual Property Rights in Bilateral Investment Treaties' (n 494) 559; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 226; Morin JF (n 496) 42.

⁵⁴² Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 226.

As the gathering of clinical test data is a time and cost expensive process, TRIPS-Plus FTAs frequently aim to protect the investments of research-based pharmaceutical companies by explicitly preventing generic manufacturers from relying on an originator company's test data for marketing approval applications of generics, during specified data exclusivity periods.⁵⁴³ The Trans-Pacific Partnership Agreement (TPP), for example, provides that third parties shall not be permitted to use such data, without the consent of the rights holder, for a period of at least five years.⁵⁴⁴ This five year data exclusivity period shall further be applicable where a country relies on test data submitted for marketing approval in another country.⁵⁴⁵ While most FTAs require at least this five-year data exclusivity period, certain agreements, like the TPP, go even further, by requiring additional three-year protection periods for data submitted for the marketing approval of new uses of prior known products.⁵⁴⁶

Data exclusivity is automatically granted and constitutes an independent IP right applicable to pharmaceuticals irrespective of patent status, providing protection where a patent is expired, no patent was filed for, and even for unpatentable inventions.⁵⁴⁷ This protection, however, does not prevent other corporations from submitting their own test data.⁵⁴⁸ As the required clinical trials, however, are lengthy and expensive, generic manufacturers regularly lack the resources to conduct this research.⁵⁴⁹ Even where a manufacturer is capable of accumulating the required data, the costs involved can significantly increase the price of generic drugs.⁵⁵⁰ Consequently, data exclusivity provisions are liable to directly impair the affordability of medicines in developing countries by delaying the introduction of generic competition.⁵⁵¹ As indicated above in 2.4.4, It is further submitted that the rather unnecessary repetition of clinical trials

⁵⁴³ Ho CM (n 31) 241-242; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 227; Morin JF (n 496) 41; Stuhldreier M (n 119) 178.

⁵⁴⁴ The Trans-Pacific Partnership Agreement (signed 04 February 2016, not ratified as US withdrew its signature) [TPP], Article 18.50.1(a); cf. Stuhldreier M (n 119) 179.

⁵⁴⁵ TPP (n 544) Article 18.50.1(b); cf. Stuhldreier M (n 119) 179.

⁵⁴⁶ cf. TPP (n 544) Article 18.50.2(a); Lopert R and Gleeson D (n 490) 201; Morin JF (n 496) 42; Sell SK (n 488) 60; Stuhldreier M (n 119) 179.

⁵⁴⁷ Ho CM (n 31) 242, Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 228; Bernieri RC, 'Intellectual Property Rights in Bilateral Investment Treaties' (n 494) 559.

⁵⁴⁸ Ho CM (n 31) 242; Sell SK (n 488) 60; Stuhldreier M (n 119) 179.

⁵⁴⁹ Ho CM (n 31) 245; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 227.

⁵⁵⁰ Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 227.

⁵⁵¹ Stuhldreier M (n 119) 179; Townsend B, Gleeson D, and Lopert R (n 497) 687.

on human beings is ethically hardly justifiable, as the safety of the products has already been established.⁵⁵²

2.5.1.4 Restrictions of TRIPS Exceptions

TRIPS-Plus FTAs can further limit the exceptions provided by the TRIPS Agreement.⁵⁵³ The ability of governments to facilitate exceptions to patent rights – like the Bolar exception, as discussed above in 2.4.3.6 – is of particular importance for the protection of public health.⁵⁵⁴ While under TRIPS, governments are free to provide such exceptions with the main limitation being that this should not unreasonably conflict with the normal exploitation of patents, TRIPS-Plus provisions can limit eligible exceptions to specific permissible categories, thereby restricting the flexibility of governments to self-determine suitable grounds.⁵⁵⁵

While US FTAs for example, explicitly allow for the use of the Bolar exception, they commonly simultaneously limit eligible exceptions, only permitting the production of generic patented medicines for purposes of marketing approval.⁵⁵⁶ According to a group of congressmen, parties to those FTAs can also only facilitate the export of such products for marketing approval purposes.⁵⁵⁷ If this holds true, such provisions would effectively render the export solution of Article 31*bis* TRIPS – as discussed above in 2.4.3.8 – useless, as FTA members with pharmaceutical production capacity would be prevented from exporting generic medicines, produced under a compulsory license, to countries without adequate production capacity.⁵⁵⁸

2.5.1.5 Restrictions of Compulsory Licensing

TRIPS-Plus FTAs commonly include provisions that may either directly or indirectly affect the ability of governments to make use of compulsory licensing. Direct

⁵⁵² Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 227.

⁵⁵³ Ho CM (n 31) 235.

⁵⁵⁴ Bernieri RC, 'Intellectual Property Rights in Bilateral Investment Treaties' (n 494) 555.

⁵⁵⁵ Bernieri RC, 'Intellectual Property Rights in Bilateral Investment Treaties' (n 494) 556; Ho CM (n 31) 239-240; Morin JF (n 496) 45.

⁵⁵⁶ Morin JF (n 496) 45.

⁵⁵⁷ *ibid* 46.

⁵⁵⁸ *ibid*.

implications can derive from provisions aimed at limiting the right to and reasons for issuing compulsory licenses to specific grounds, while indirect implications can be introduced by regulations not directly aiming at, but implicitly creating obstacles to the utilisation of compulsory licenses, such as data exclusivity provisions, or investment protection clauses.⁵⁵⁹ As discussed above in 2.4.3.7 and 2.4.3.8, the interpretation of how compulsory licenses can successfully be used is already complicated under Articles 31 and 31*bis* TRIPS. Additional controversy introduced by TRIPS-Plus standards can further compromise the effective utilisation of such licenses for the protection of public health in developing countries, disregarding the purpose of the Doha Declaration.⁵⁶⁰

TRIPS-Plus agreements often aim to limit the applicability of compulsory licenses to specific situations, thereby restricting the freedom of WTO members under TRIPS and the Doha Declaration to self-determine the grounds upon which compulsory licenses can be granted.⁵⁶¹ Such limitations frequently only permit the grounds explicitly referred to in the Doha Declaration, namely national emergencies, situations of extreme urgency, and public non-commercial use.⁵⁶² Some FTAs go even further by restricting the use of compulsory licensing to the specific diseases of HIV/AIDS, tuberculosis, malaria, and other epidemics, i.e. only the examples provided by the Doha Declaration, even though the declaration's list is non-exhaustive.⁵⁶³ Moreover, while under TRIPS, rights holders are entitled to receive an adequate compensation when their patents are affected by compulsory licenses, some TRIPS-Plus agreements require that patent owners receive reasonable or even full compensation.⁵⁶⁴ Particularly, the requirement of full compensation seems to defeat the purpose of compulsory licensing for public health reasons, as the aim of such licenses is to make urgently required medicines as cheap as possible.

⁵⁵⁹ Abbott FM and Reichman JH (n 313) 963; Bernieri RC, 'Compulsory Licensing and Public Health' (n 486) 3-4; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 231.

⁵⁶⁰ Bernieri RC, 'Compulsory Licensing and Public Health' (n 486) 1.

⁵⁶¹ cf. Gumbel M (n 322) 172; Ho CM (n 31) 237; Lopert R and Gleeson D (n 490) 202; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 231.

⁵⁶² Bernieri RC, 'Intellectual Property Rights in Bilateral Investment Treaties' (n 494) 556; Ho CM (n 31) 238; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 231.

⁵⁶³ Sell SK (n 488) 62; Lopert R and Gleeson D (n 490) 201-202.

⁵⁶⁴ Bernieri RC, 'Intellectual Property Rights in Bilateral Investment Treaties' (n 494) 556; Ho CM (n 31) 238; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 231.

Furthermore, certain FTAs, such as the TPP, introduced investor-state dispute settlement (ISDS) proceedings. Such proceedings enable private corporations to directly challenge states over treaty breaches, without the need to rely on their home states to do so, as would be required under the WTO DSU.⁵⁶⁵ Thereby, patent owners can directly challenge policy decisions aimed at the protection of public health, including compulsory licenses, as well as the determined amount of compensation, adding even more uncertainty.⁵⁶⁶ As ISDS proceedings usually incur high costs, developing countries in particular, might become even more reluctant to pursue the granting of compulsory licenses, even where this would be justified, due to the fear of expensive litigation.⁵⁶⁷ Therefore, the mere possibility of private investors being able to challenge policy decisions taken in the interest of the population seems dangerous and potentially anti-democratic.⁵⁶⁸

Additionally, data exclusivity provisions in particular, can interfere with the effectiveness of compulsory licenses both under Article 31 TRIPS and under the waiver system of Article 31*bis* TRIPS. There is a certain controversy regarding whether compulsory licenses provide exceptions to data exclusivity provisions.⁵⁶⁹ It generally seems that compulsory licenses only affect patents as regulated under Part II Section 5 TRIPS, arguably not, however, data exclusivity provisions under Part II Section 7 TRIPS, as data exclusivity constitutes its own category of IP rights alongside patents.⁵⁷⁰ While generic medicines produced under compulsory licenses nevertheless need to receive marketing approval, TRIPS-Plus data exclusivity provisions can prevent generic manufacturers from relying on data submitted by the originator company for the duration of a specified data exclusivity period, as discussed above in 2.5.1.3.⁵⁷¹ Further, some FTAs explicitly provide that patent holders may not be required to disclose specific clinical information and know-how even in cases where compulsory licenses are granted for national emergencies.⁵⁷² As a result, to operate under compulsory licenses, generic manufacturers are required to conduct their own

⁵⁶⁵ Stuhldreier M (n 119) 187.

⁵⁶⁶ Bernieri RC, 'Compulsory Licensing and Public Health' (n 486) 17; Lopert R and Gleeson D (n 490) 209.

⁵⁶⁷ Lopert R and Gleeson D (n 490) 209.

⁵⁶⁸ Stuhldreier M (n 119) 195.

⁵⁶⁹ Morin JF (n 496) 42.

⁵⁷⁰ Mitchell A, Voon T, and Whittle D (n 522) 299-300; Sell SK (n 488) 60; Stuhldreier M (n 119) 178-179.

⁵⁷¹ Lopert R and Gleeson D (n 490) 201; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 228.

⁵⁷² Morin JF (n 496) 47.

clinical trials which substantially delays the availability of cheaper generic products, increases their costs, and further requires the unethical repetition of human trials.⁵⁷³

Consequently, TRIPS-Plus FTAs can directly limit a government's ability to facilitate compulsory licenses, and further indirectly jeopardise their effective utilisation for the protection of public health, potentially defeating their very purpose. This may result in a further aggravation of the already existing uncertainty regarding the use of compulsory licenses, potentially making governments overly cautious, which may lead to developing countries completely refraining from their utilisation.⁵⁷⁴ Ultimately, because the TRIPS Agreement provides no sufficient safeguards preventing FTAs from limiting the applicability of compulsory licenses and the export solution, TRIPS-Plus provisions can be systematically used to undermine public health objectives that restrict the rights of patent holders.⁵⁷⁵

2.5.1.6 Patent Linkage

Under patent linkage regulations, the marketing approval of medicines is linked to their patent status, providing that regulatory approval has to be declined when the marketing of a product would interfere with an existing patent, unless the patent owner of the latter consents.⁵⁷⁶ This creates new responsibilities for regulatory authorities which commonly lack relevant expertise in the field of IP law.⁵⁷⁷ Traditionally, the owners of private rights – the category to which patent rights belong – are self-responsible for initiating their enforcement. Patent linkage provisions thus give patent holders a major advantage by diverting this responsibility to the regulatory authorities.⁵⁷⁸

Patent linkage is further particularly criticised for the adverse impacts it may potentially have on generic drugs produced under compulsory licenses.⁵⁷⁹ As

⁵⁷³ Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 229; Morin JF (n 496) 47; Townsend B, Gleeson D, and Lopert R (n 497) 687.

⁵⁷⁴ Bernieri RC, 'Compulsory Licensing and Public Health' (n 486) 20; Stuhldreier M (n 119) 195.

⁵⁷⁵ Dutfield G, 'Delivering Drugs to the Poor' (n 356) 124.

⁵⁷⁶ Abbott FM and Reichman JH (n 313) 963; Lopert R and Gleeson D (n 490) 201; Ho CM (n 31) 242; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 224; Sell SK (n 488) 62.

⁵⁷⁷ Ho CM (n 31) 243; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 225; Townsend B, Gleeson D, and Lopert R (n 497) 687.

⁵⁷⁸ Ho CM (n 31) 243; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 225.

⁵⁷⁹ Abbott FM and Reichman JH (n 313) 963; Lopert R and Gleeson D (n 490) 201.

compulsory licenses do not affect the validity of a patent, and as patent linkage provisions commonly do not address the issue of compulsory licensing, patent linkage provisions require that the marketing approval of any generic drug has to be declined while a patent is in force, even when produced under a compulsory license.⁵⁸⁰ While a solution to this problem may potentially be found in form of an exception for the protection of public health, an initial refusal and the concomitant litigation can significantly delay the effectiveness of compulsory licenses.

2.5.2 Impacts of TRIPS-Plus Provisions

The world has reversed from the global WTO and WIPO stage, back to an era of bilateral and multilateral IP rights negotiations.⁵⁸¹ While in general, TRIPS-Plus provisions are only applicable to member states of the relevant agreement, it has been suggested that FTAs can lead to a global ratcheting up of IP standards.⁵⁸² The higher protection provided by TRIPS-Plus agreements is not limited to rights holders from contracting parties, as according to the MFN treatment, under Article 4 TRIPS, as discussed above in 2.2, the same extended protection has to be granted to rights holders from any WTO member.⁵⁸³ Further, when enough countries implement higher IP protection, or when a large number of FTAs include similar TRIPS-Plus provisions, those regulations can *de facto* turn into new global standards.⁵⁸⁴ Accordingly, FTAs can lead to a steady increase of international IP protection levels.⁵⁸⁵

Furthermore, certain FTAs require their members to always adopt the highest international standards of IP protection. Such FTAs can systematically proliferate minimum standards, as members to an initial agreement have to implement higher

⁵⁸⁰ Abbott FM, 'The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements' (April 2004) Quaker United Nations Office, Occasional Paper 14
<https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1977300> accessed 27 May 2019, 8; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 226; Sell SK (n 488) 61-62.

⁵⁸¹ Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 216.

⁵⁸² *ibid* 222; Drahos P, 'Expanding Intellectual Property's Empire: The Role of FTAs' (November 2003) <<https://www.ictsd.org/sites/default/files/downloads/2008/08/drahos-fta-2003-en.pdf>> accessed 27 May 2019, 7.

⁵⁸³ Frankel S (n 489) 1032 and 1040; Gumbel M (n 322) 172; Ho CM (n 31) 225; Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 223.

⁵⁸⁴ Frankel S (n 489) 1035 and 1039-1040.

⁵⁸⁵ *ibid* 1034.

protection standards from subsequent agreements, even where they are not involved in the negotiation process.⁵⁸⁶ If a hypothetical FTA between the US and Vietnam, for example, required the parties to always adopt the highest international standard of IP protection, and the US later concluded an agreement with Nigeria introducing higher patent protection than the US-Vietnam FTA, Vietnam would be required to provide the same level of patent protection as Nigeria. Consequently, as members of such FTAs will always be required to implement the highest international level of IP protection, those standards will effectively become new international minimum standards from which any future debates on IP laws in a global forum have to start.⁵⁸⁷

As they are commonly pushed by industrialised nations, TRIPS-Plus FTAs are designed to best represent those countries' interests, omitting the concerns of the developing world.⁵⁸⁸ In particular, FTA negotiations are strategically used for segmenting developing country coalitions, and subsequently exploiting power imbalances between developed and developing countries.⁵⁸⁹ As FTAs are furthermore frequently negotiated in secret, developing countries can be cut off from NGO support, further weakening advancements made in the area of public health protection at the WTO level.⁵⁹⁰ Additionally, less consideration might be given to the general implications of TRIPS-Plus standards, as scholars and experts have no access to secret documents underpinning negotiations prior to their conclusion.⁵⁹¹

The TRIPS Agreement intended to balance the interests of rights holders with the broader public interest.⁵⁹² Under TRIPS-Plus provisions, however, this balance is likely to be neglected.⁵⁹³ While the WTO approach to interpreting TRIPS became increasingly contributory to the protection of public health, FTAs tend to have their own ways of interpretation with potentially detrimental outcomes for public health.⁵⁹⁴ Although TRIPS-Plus provisions should not be used to circumvent the objectives and principles of Articles 7 and 8 TRIPS, and the Doha Declaration, FTAs may in fact

⁵⁸⁶ Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 223.

⁵⁸⁷ *ibid* 223 and 235; Bernieri RC, 'Intellectual Property Rights in Bilateral Investment Treaties' (n 494) 560.

⁵⁸⁸ Mercurio B, 'TRIPS-Plus Provisions in FTAs' (n 491) 220.

⁵⁸⁹ *ibid* 221.

⁵⁹⁰ *cf.* Bernieri RC, 'Compulsory Licensing and Public Health' (n 486) 5; Morin JF (n 496) 40; Sell SK (n 488) 58.

⁵⁹¹ Ho CM (n 31) 228.

⁵⁹² *ibid* 200.

⁵⁹³ *ibid* 251; Xiong P (n 509) 172.

⁵⁹⁴ Xiong P (n 509) 155.

have exactly this effect, so that a conflict between TRIPS and TRIPS-Plus standards is likely to arise.⁵⁹⁵ Due to the enhanced IP protection in TRIPS-Plus agreements, the interpretations of these will inevitably deviate from TRIPS.⁵⁹⁶ This concern is particularly problematic with respect to FTAs that establish their own dispute settlement systems to deal with TRIPS-Plus IP disputes, potentially ignoring WTO interpretations aimed at the protection of public health.⁵⁹⁷

While under international trade law, TRIPS-Plus is a perfectly lawful means to go beyond the regulations of TRIPS, stronger IP protection generally has detrimental impacts on public health.⁵⁹⁸ By extending the monopolistic positions of patent owners, TRIPS-Plus standards are responsible for delaying the market entry of cheaper generic medicines, thereby increasing health-care costs for governments and limiting the accessibility of medicines, with little or no added benefits for developing countries.⁵⁹⁹ Likewise, TRIPS-Plus FTAs can jeopardise the efficacy of compulsory licenses and the export solution.⁶⁰⁰ Additionally, extended patent protection may further hamper innovative advances in the medical field by competitors, and the possibility of patent evergreening can delay the disclosure of new treatment methods.⁶⁰¹ Given these points, TRIPS-Plus FTAs are eminently harmful for poorer developing countries without public healthcare systems or insurance, where major parts of the population are already incapable of acquiring urgently required medications.⁶⁰²

2.6 Concluding Remarks

After briefly introducing the evolution of the international IP and patent regime, this chapter provided an overview and interpretation of the scope of the patent related

⁵⁹⁵ Atik J (n 485) 1; Grosse Ruse-Khan H (n 507) 330; Xiong P (n 509) 155 and 162.

⁵⁹⁶ Xiong P (n 509) 162.

⁵⁹⁷ cf. *ibid* 156.

⁵⁹⁸ Ho CM (n 31) 250; Morin JF (n 496) 50.

⁵⁹⁹ Atik J (n 485) 5; Lopert R and Gleeson D (n 490) 201; Townsend B, Gleeson D, and Lopert R (n 497) 683.

⁶⁰⁰ Bernieri RC, 'Intellectual Property Rights in Bilateral Investment Treaties' (n 494) 553; Lopert R and Gleeson D (n 490) 201.

⁶⁰¹ cf. Richards DG, 'A Skeptik's View of Intellectual Property Rights' in Bird RC and Jain SC (eds), *The Global Challenge of Intellectual Property Rights* (Edward Elgar Publishing 2008) 268 and 280; Stuhldreier M (n 119) 184-185; United Nations Economic and Social Council (ECOSOC), 'The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights' (27 June 2001) Un Doc E/CN.4/Sub.2/2001/13, para 40.

⁶⁰² cf. Ho CM (n 31) 250; Lopert R and Gleeson D (n 490) 207-208.

provisions of the TRIPS Agreement in light of the Doha Declaration, as well as frequently reoccurring provisions of TRIPS-Plus FTAs. In particular, this chapter has shown that the international harmonisation of IP standards under the WTO system in combination with the non-discrimination principle as to the field of technology under Article 27 TRIPS has led to the global introduction of pharmaceutical patent rights with a minimum protection period of 20 years, even in countries that formerly explicitly excluded pharmaceutical products from patentability. During this protection term, patent holders enjoy extensive exclusive rights over their patented inventions, basically granting them monopolistic positions on the markets. To counterbalance these excessive rights, the TRIPS Agreement provides a number of flexibilities and exceptions that can be utilised by governments for the protection of the public interest. As elaborated in this chapter, however, these flexibilities and exceptions are considerably restricted by the narrow limitations attached to their applicability, which create obstacles for their effective utilisation. Additionally, the use of the TRIPS flexibilities and exceptions is frequently hampered by economic and political pressure utilised by the home states of IP holding industries, commonly discouraging developing countries from exercising their rights to restrict IP rights in the public interest. This economic and political pressure in combination with extensive lobbying activity by powerful corporations has further led to a constant proliferation of IP and patent standards through so-called TRIPS-Plus provisions in FTAs. This proliferation is possible, because the TRIPS Agreement only defines minimum protection standards, without defining any limitations as to appropriate ceilings of protection, which led to a further strengthening of the rights of IP and patent owners. In particular, TRIPS-Plus standards tend to relax patentability requirements, and explicitly restrict the use of flexibilities and exceptions, thereby aggravating the already detrimental impacts of the patentability of pharmaceutical products. The problems brought about by the global introduction of pharmaceutical patent rights, and particularly their detrimental impacts on the realisation of the right to health, will be further scrutinised in Part II of this thesis, aiming to identify whether the current international patent regime can be regarded as justified, and how the system can be improved to better balance the private rights of inventors with wider public interests.

Part II: Analysing the Issues

Chapter Three

3 The Legal and Moral Relationship between Human Rights and the International IP Regime

Part I of this thesis provides a brief overview of the legal framework, elaborating on the right to health under international human rights law, and the international patent regime established by the TRIPS Agreement, and TRIPS-Plus agreements. Part II of this thesis analyses the justification of the current international patent regime, and addresses whether and if so, how the system of pharmaceutical patentability can be improved. Before examining the justification of the international patent regime in chapter 4, however, it is of crucial importance to establish the parameters against which this justification can be scrutinised.

Firstly, in regard to the detrimental impacts of pharmaceutical patents on the realisation of the right to health, it is necessary to consider whether there exists a hierarchy in international law prioritising either human rights or trade law; under the latter of which current international IP and patent rights are regulated. Secondly, it is necessary to consider whether IP may constitute a human right, and if so, whether human rights law provides for an intra-regime hierarchy that prioritises certain fundamental human rights above less-essential rights in cases of norm conflicts. To this end, the analyses provided by the first part of this chapter addresses Research Question 1:

What is the relationship between international human rights law and international IP/trade law?

After indicating that such a legal hierarchy currently cannot be established, the second part of this chapter analyses whether other, non-legal considerations may suggest the

legitimacy of prioritising certain fundamental human rights above conflicting norms of international IP law. In this regard, this thesis analyses moral reasons, which may reinforce the vital importance of those human rights that protect human life and well-being, justifying the prioritisation of such rights based on the concept of human dignity. The second part of this chapter then aims to answer Research Question 2:

Are there valid moral principles that can be utilised to justify the prioritisation of the right to health over contradictory provisions of international trade law and patent law?

3.1 The Relationship between International Human Rights Law and International Trade and IP Law

3.1.1 The Scope of International Human Rights Law

Following the atrocities of the second World War, human rights have been integrated at the centre of the international community, soon becoming a cornerstone of public international law.¹ Human rights are inherently connected to human dignity and held by all human beings without discrimination, solely founded on the virtue of humanity.² While human rights are based on the fundamental value of human dignity, and give rise to special moral claims justified by fundamental and universal human interests that do not derive their validity from their recognition by positive law, they require further elaboration by legal provisions to facilitate their meaningful acknowledgement and protection.³ Nevertheless, it is embedded in the nature of human rights, as ‘self-evident’ moral norms, that their legitimacy is not dependent on their recognition by any form of contract or positive law, so that human rights exist even where an authority denies their recognition.⁴ They are described as equal and universal ethical principles, applying to all humans in all places, recognising the equal worth of all human beings.⁵

¹ Ziegler AR and Boie B, ‘The Relationship between International Trade Law and International Human Rights Law’ in de Wet E and Vidmar J (eds), *Hierarchy in International Law: The Place of Human Rights* (OUP 2012) 272.

² Woods K, *Human Rights* (Palgrave MacMillan 2014) 5.

³ cf. ibid 20 and 69; de Feyter K, *Human Rights: Social Justice in the Age of the Market* (Zed Books 2005) 60; Freeman M, *Human Rights: An Interdisciplinary Approach* (2nd edn, Polity Press 2011) 67.

⁴ Woods K (n 2) 5 and 7.

⁵ ibid 6-7; O’Byrne DJ, *Human Rights: An Introduction* (Pearson Education 2003) 26-27.

In regard to this universal applicability, it is generally held that human rights cannot be voluntarily surrendered.⁶

The recognition of human rights entails counterpart duties and obligations.⁷ While the main duty bearers under international human rights law are sovereign states, the nature of human rights implies duties on everyone as a society.⁸ It is often held, however, that international human rights law does not impose duties on non-state actors.⁹ In contrast, Article 1 of the Universal Declaration on Human Rights (UDHR) provides that all human beings ‘should act towards one another in a spirit of brotherhood.’¹⁰ Further, Article 29 UDHR explicitly provides that ‘[e]veryone has duties to the community in which alone the free and full development of his personality is possible.’¹¹ The wording of the UDHR implies that everyone as a bearer of human rights has concomitant obligations towards the realisation of the human rights of everyone else. The interpretation that human rights law is supportive of the accountability of actors other than states, however, is not unanimous. Opposition is even raised by human rights lawyers apprehensive that such an interpretation may weaken the integrity of human rights.¹² In particular, both the fact that the binding nature of the UDHR – as discussed in the next section – is disputed, as well as the use of the term ‘should’ in Article 1, indicate that legal obligations of non-state actors cannot be derived from the UDHR alone.

3.1.1.1 The Binding Nature of International Human Rights Treaties

Further controversy exists regarding the direct binding nature of international human rights obligations. Being merely a declaration, it seems that the UDHR itself is of an aspirational rather than a directly legally binding nature.¹³ At the same time it can be submitted that due to its nature, its historic importance, its widespread acceptance, as well as through state practice, and *opinio juris*, the UDHR has now become part of customary international law, thereby receiving the status of a binding legal

⁶ Woods K (n 2) 6.

⁷ *ibid* 20.

⁸ *cf.* *ibid* 8.

⁹ de Feyter K (n 3) 1.

¹⁰ The Universal Declaration on Human Rights (adopted 10 December 1948) [UDHR], Article 1.

¹¹ *ibid* Article 29(1).

¹² de Feyter K (n 3) 32.

¹³ Woods K (n 2) 7; O’Byrne DJ (n 5) 26.

document.¹⁴ This view can be supported by considering that the UDHR, in combination with the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR) form the International Bill of Rights, i.e. the decisive origin of international human rights law.¹⁵ To have legal legitimacy, human rights can only be binding for states that consent to them, either by explicit agreement or by consistent practice.¹⁶ Accordingly, ‘customary international law [...] binds all states except persistent objectors.’¹⁷ The question of whether the UDHR has achieved the status of customary international law, however, has not yet been ruled upon by the international Court of Justice.¹⁸

The two international Covenants, i.e. the ICCPR and the ICESCR, by way of contrast, are voluntarily accepted by states and impose legally binding obligations on their members upon ratification.¹⁹ Similarly, regional human rights treaties, such as the European Convention on Human Rights (ECHR), are legally binding for their members.²⁰ While in the view of lawyers the binding force of the covenants thus is clearly established, the sentiment of economists and political scientists may differ, suggesting that public policy is more decisive.²¹ It must be borne in mind, however, that ‘[r]atification implies consent to be bound.’²² While recognising that not all human rights norms have an entirely global reach yet, a strong case can be made, suggesting that international human rights law generally is legally binding upon states. In this regard, the Second World conference on Human Rights concluded in 1993 by establishing that ‘the universality of all human rights is beyond question.’²³

¹⁴ cf. Flinterman C, ‘Human Rights Law Status Report’ in Grosheide W (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar Publishing 2010) 38.

¹⁵ Drahoš P, ‘Intellectual Property and Human Rights’ (1999) 3 IPQ 349, 359; Flinterman C (n 14) 38; O’Byrne DJ (n 5) 89; ESCR-Net, ‘Section 5: Background Information on the ICESCR’ <<https://www.escr-net.org/resources/section-5-background-information-icescr>> accessed 23 May 2019.

¹⁶ Karamanian SL, ‘Human Rights Dimensions of Investment Law’ in de Wet E and Vidmar J (eds), *Hierarchy in International Law: The Place of Human Rights* (OUP 2012) 238.

¹⁷ de Wet E and Vidmar J, ‘Conclusions’ in de Wet E and Vidmar J (eds), *Hierarchy in International Law: The Place of Human Rights* (OUP 2012) 302.

¹⁸ de Feyter K (n 3) 59.

¹⁹ Woods K (n 2) 7; ESCR-Net, ‘Section 5’ (n 15).

²⁰ Woods K (n 2) 7.

²¹ Freeman M (n 3) 181.

²² de Feyter K (n 3) 49.

²³ Flinterman C (n 14) 38.

3.1.1.2 The Binding Nature of CESCR Comments and Interpretations

While accepting the general binding nature of international human rights laws, it has to be acknowledged that the universality of human rights is not equal to uniformity of interpretation, and that historical contexts and the convictions of individual countries have to be accounted for.²⁴ Thus, recognising that different cultural contexts may lead to diverging interpretations of specific human rights provisions, it is important to identify whether universally valid legally binding human rights interpretations may exist. In the context of the right to health, and the importance of CESCR General Comment No. 14 for its interpretation, the following analysis scrutinises the validity of the General Comments provided by the Committee on Economic, Social and Cultural Rights (CESCR).

The CESCR has attempted to clarify the vagueness of the original ICESCR treaty obligations, inter alia by providing General Comments on specific provisions thereof. As indicated in chapter 1.2, General Comments provide expedient guidance on how the ICESCR should be implemented, but while governments and national courts are recommended to acknowledge their authority, from a strictly legal perspective they are not binding.²⁵ States are therefore free to decide for themselves whether they accept the Committee's interpretations.²⁶ At the same time, UN treaty bodies like the CESCR consist of experts in the relevant fields and, at an international level, constitute the principal non-political interpreting, monitoring and enforcement bodies of those treaties.²⁷ As stipulated by Article 26 of the Vienna Convention on the Law of Treaties

²⁴ *ibid* 38-39.

²⁵ Bódig M, 'Soft Law, Doctrinal Development, and the General Comments of the UN Committee on Economic, Social and Cultural Rights' in Lagoutte S, Gammeltoft-Hansen T, and Cerone J (eds), *Tracing the Roles of Soft Law in Human Rights* (OUP 2016) 69; de Feyter K (n 3) 48; McCall-Smith KL, 'Interpreting International Human Rights Standards: Treaty Body General Comments as a Chisel or a Hammer' in Lagoutte S, Gammeltoft-Hansen T, and Cerone J (eds), *Tracing the Roles of Soft Law in Human Rights* (OUP 2016) 30.

²⁶ de Feyter K (n 3) 49.

²⁷ McCall-Smith KL (n 25) 27 and 29.

(VCLT), states have the duty to perform treaty obligations in good faith, which arguably requires the cooperation with UN treaty bodies.²⁸

CESCR General Comments fall within the category of soft-law, and imply a certain degree of normative force despite their non-binding character.²⁹ The general lack of enforceability of international human rights law and the vagueness of many treaty provisions – as scrutinised in further detail in the next sub-chapter – have created the requirement for soft-law instruments to provide guidance on adequate interpretation.³⁰ Particularly when considered in national or regional courts, General Comments can gradually turn from soft law instruments towards the direction of binding interpretations, thereby filling gaps in treaty provisions.³¹ Notably, the European Court of Human Rights (ECtHR), as the primary human rights court in Europe, is frequently expeditious in referencing treaty body recommendations and comments, which support their validity and the recognition of human rights law as an evolving field that cannot be viewed as a self-contained system.³² Therefore, CESCR General Comments have been acknowledged as serving as important tools for addressing shortcomings of the ICESCR's treaty text by clarifying specific human rights obligations.³³ They operate as norm-filling where relevant binding treaty provisions require a clarification of the commitments of the various actors.³⁴ It must be noted, however, that CESCR General Comments can sometimes come into collision with the original doctrinal content of the treaty.³⁵ Therefore, not all courts follow CESCR General Comments, with some providing alternative interpretations, indicating that there are legitimate diverging opinions.³⁶

The question of how authoritative these General Comments truly are, therefore cannot be unanimously answered. While supporters of their validity acknowledge the

²⁸ *ibid* 30; Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) [VCLT], Article 26.

It must be noted here that the VCLT only requires the performance of treaty obligations in good faith but does not directly refer to treaty specific monitoring mechanisms such as General Comments. See thereto: McCall-Smith KL (n 25) 34.

²⁹ Gammeltoft-Hansen T, Lagoutte S, and Cerone J, 'Introduction: Tracing the Roles of Soft Law in Human Rights' in Lagoutte S, Gammeltoft-Hansen T, and Cerone J (eds), *Tracing the Roles of Soft Law in Human Rights* (OUP 2016) 1.

³⁰ *ibid* 6; Bódig M (n 25) 70 and 74; Drahoš P (n 15) 361.

³¹ McCall-Smith KL (n 25) 33-34.

³² *ibid* 42 and 45.

³³ Gammeltoft-Hansen T, Lagoutte S, and Cerone J, 'Introduction' (n 29) 10.

³⁴ *ibid* 6 and 8; McCall-Smith KL (n 25) 28.

³⁵ Bódig M (n 25) 71.

³⁶ McCall-Smith KL (n 25) 46.

authoritative nature of their interpretations, critics consider these interpretations as arbitrary and thus not qualifying for legal recognition.³⁷ Furthermore, in their opposition to the validity of the General Comments, certain states argue that they overstep the authority of the CESCR.³⁸ As most human rights treaties, however, explicitly establish that monitoring bodies can provide interpretations by issuing recommendations and General Comments as part of the ‘communication and cooperation between state parties and treaty bodies’,³⁹ it can generally be submitted that the CESCR simply carries out its duty under the treaty text.⁴⁰

General Comments, however, often tend to go beyond their norm-filling objective by engaging in normative development or norm creation.⁴¹ While this invites criticism and opposition, it must be acknowledged that normative development is essential for human rights doctrine in order to ensure that human rights are capable of adequately addressing current challenges.⁴² To be meaningful, CESCR interpretations therefore need to refine treaty terms in order to elaborate human rights in context of the ever-changing environment.⁴³ This practice of evolutive interpretation is supported by the ECtHR, and the principle of positive interpretation is similarly recognised by Article 31(1) VCLT.⁴⁴ Nevertheless, when General Comments depart too much from state practice and existing treaty obligations, the authoritative status of their interpretations may be disputed.⁴⁵ Furthermore, while the purpose and subjects of General Comments may generally seem appropriate, they can lead to doctrinal and political dissonance.⁴⁶ In particular states with lower human rights standards than those suggested by General Comments tend to oppose their validity as they feel exposed by them.⁴⁷

In conclusion, it must therefore be acknowledged that the authority and legal value of CESCR General Comments remains disputed, and that a unitary legal boundness

³⁷ *ibid* 31.

³⁸ *ibid* 32.

³⁹ Bódig M (n 25) 73.

⁴⁰ McCall-Smith KL (n 25) 32.

⁴¹ Bódig M (n 25) 74.

⁴² *ibid*.

⁴³ *ibid* 75; McCall-Smith KL (n 25) 28.

⁴⁴ Bódig M (n 25) 75.

⁴⁵ *ibid* 84.

⁴⁶ *ibid* 69 and 87.

⁴⁷ McCall-Smith KL (n 25) 33.

cannot be established.⁴⁸ Nevertheless, it can be observed that General Comments constitute a substantive means for refining human rights doctrine by challenging states' practice without constraining their sovereignty.⁴⁹

3.1.1.3 The Enforceability of Human Rights

The international human rights system 'lacks the power to enforce compliance.'⁵⁰ Its major weakness is that it is therefore highly dependent on politics, and that without the existence of a specialised court enforcing the Bill of Rights, international human rights law relies on the willingness of states to uphold it.⁵¹ As political action, however, represents the impact of power relationships, human rights are often neglected as a direct consequence of this power play.⁵²

Notably, the international human rights regime lacks mechanisms by which individuals can seek redress for general human rights violations on an international level, and those enforcement measures that are currently available cannot influence governments in the same way as binding court judgments.⁵³ This weakness is deeply embedded in the UN regime, with the UN Commission on Human Rights only adopting non-binding resolutions applying strategies of naming and shaming.⁵⁴ Similarly, the decisions of the committees of the two international covenants adopt instruments for monitoring human rights violations that are recommendatory only.⁵⁵ The effective enforcement of human rights law is thereby shifted to regional and national jurisprudence.

Furthermore, economic and social human rights have been regarded as mere policy prescriptions due to their interdependence on available resources.⁵⁶ Claims have been made in this regard, suggesting that economic and social rights are not justiciable, even though case law suggests otherwise.⁵⁷ In particular Article 2(1) ICESCR, which

⁴⁸ *ibid* 45.

⁴⁹ Bódig M (n 25) 85.

⁵⁰ de Feyter K (n 3) 42.

⁵¹ *ibid* 3 and 31; O'Byrne DJ (n 5) 90.

⁵² *cf.* de Feyter K (n 3) 31.

⁵³ *ibid* 32-33.

⁵⁴ *ibid* 32; Bódig M (n 25) 83.

⁵⁵ Brown AEL, *Intellectual Property, Human Rights and Competition: Access to Essential Innovation and Technology* (Edward Elgar Publishing 2012) 55; de Feyter K (n 3) 32.

⁵⁶ de Feyter K (n 3) 43.

⁵⁷ Freeman M (n 3) 181.

facilitates the progressive realisation of economic and social human rights, may undermine their enforceability by providing an easy defence for non-compliance.⁵⁸ Therefore, it seems that the enforceability of economic and social rights is particularly limited, and can only be effective when supported by political action.⁵⁹ In the era of globalisation, human rights have further suffered from their limited ability to come to terms with new challenges arising from the international economic order and transnational economic actors.⁶⁰ Even where legal remedies exist, all too often the most vulnerable and marginalised groups of society face the greatest obstacles when seeking legal redress for human rights violations.⁶¹

The situation is somewhat different for regional human rights protection, for example in the Americas and Europe, where the relevant treaties have specialised regional human rights courts, which provide for more effective enforcement mechanisms by adopting binding rulings.⁶² While regional human rights enforcement can thus serve as an example of how human rights protection should effectively work, the scope of regional judgements only concerns regional treaty law and international treaties in a regional context, and is therefore not referable to human rights disputes outside these regions.

3.1.2 The Scope of International Trade and IP Law

3.1.2.1 The Scope and Enforceability of WTO Law and FTAs

As international trade law and international IP law derive from multinational or international treaty law to which states expressly consent, for example in WTO trade agreements, they are of a directly binding nature for the member states of such agreements.⁶³ While this is in general very similar to human rights treaty law, in comparison to UN human rights law, WTO law is more easily enforceable as the WTO can directly impose valid sanctions on member states that violate treaty provisions.⁶⁴

⁵⁸ cf. Bódig M (n 25) 85; de Feyter K (n 3) 47.

⁵⁹ Freeman M (n 3) 181.

⁶⁰ cf. de Feyter K (n 3) 5.

⁶¹ cf. *ibid* 24.

⁶² *ibid* 35.

⁶³ cf. Drahos P (n 15) 362.

⁶⁴ Freeman M (n 3) 187.

In the context of international law, the WTO Dispute Settlement Understanding (DSU) provides an exceptionally strong enforcement mechanism to ensure compliance with WTO trade law, as discussed in chapter 2.4.1.⁶⁵ As the power of WTO enforcement mechanisms can thus significantly exceed the power of democratically elected governments, the WTO can have considerable influence over public policy decisions.⁶⁶ Similarly, most free trade agreements (FTAs) implement their own arbitration system dealing with disputes under the agreements, thereby establishing effective enforcement mechanisms.⁶⁷

3.1.2.2 Intellectual Property as a Human Right

Before scrutinising the concept of intellectual property as a human right, it needs to be noted that in the domain of industrial property rights,⁶⁸ patents these days are commonly held by corporations – the employer of an inventor – rather than by the individual inventors themselves.⁶⁹ Therefore, when considering the concept of intellectual property as a human right, it is important to consider whether corporations can be beneficiaries of human rights law. This is a controversial issue, as human rights are inherently connected to human dignity, recognising the equal worth of all human beings, aiming at the protection of fundamental human interests. Corporations, on the contrary, are legal entities and not human beings. If it is then proposed that human rights can be held by corporations, there is a risk that if such rights conflict with the rights of natural persons, the protection of human life in dignity is jeopardised.⁷⁰ It is therefore questionable whether IP rights held by corporations should be conceded the status of human rights.⁷¹

⁶⁵ de Feyter K (n 3) 8.

⁶⁶ *ibid* 15-16.

⁶⁷ cf. Stuhldreier M, 'The Trans-Pacific Partnership Agreement and its Threats to the Affordability of Medical Products in Developing Countries' (2016) 19 *Trinity C.L. Rev.* 175, 187-191.

⁶⁸ As mentioned in note 11 in the introduction to this thesis, IP rights can be subdivided into specific categories, including 'industrial property rights', the category to which patents belong.

⁶⁹ cf. Gordon WJ, 'Current Patent Laws cannot claim the Backing of Human Rights' in Grosheide W (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar Publishing 2010) 167; WIPO, 'Frequently asked Questions: Patents' <https://www.wipo.int/patents/en/faq_patents.html> accessed 23 May 2019.

⁷⁰ de Feyter K (n 3) 46.

⁷¹ Grosheide W, 'General Introduction' in Grosheide W (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar Publishing 2010) 26.

As IP rights can also be held by natural persons, the controversy surrounding the question of whether IP rights constitute human rights is even deeper, and two main diverging views can be identified. The first sentiment suggests that by protecting private interests, IP rights are fundamentally incompatible with the public law character of human rights.⁷² Likewise, human rights generally belong to all human beings without a limitation in time, while IP rights under trade law, conversely, are subject to registration and limited in their duration.⁷³ In the light of these arguments, IP rights cannot be regarded as human rights.

The second opinion, on the contrary, contends that IP and human rights are cohesive in the sense that, similar to the human right to property more generally, human rights provide the foundation for the recognition of IP rights.⁷⁴ In effect, the perception of IP as a human right is principally based on the recognition of the human right to property, suggesting that IP is virtually identical to property in tangible assets.⁷⁵ In reality, however, there is a fundamental difference between IP and property in tangible assets, in that IP protects knowledge which is a ‘non-contentious resource’⁷⁶ that does not necessarily lose its value if it becomes more widely available.⁷⁷ If anything, the value of knowledge to society can increase, the greater its accessibility.⁷⁸ In his role as the first U.S. Patent Commissioner, Thomas Jefferson insinuated that the protection of

⁷² cf. *ibid* 5.

⁷³ Cornides J, ‘Human Rights and Intellectual Property: Conflict or Convergence?’ (2004) 7 *Journal of World Intellectual Property* 135, 146; Drahos P (n 15) 366.

⁷⁴ cf. Grosheide W, ‘General Introduction’ (n 71) 5.

⁷⁵ Cornides J (n 73) 139.

⁷⁶ Tangible goods, such as land, livestock, harvest, or producer and consumer goods, are commonly limited in their quantitative availability, and therefore ‘contentious resources’. Such goods seemingly have their highest value, both for individuals and for society, if they are privately owned, as private ownership enables the owner to reap the fruits of his/her property, and because private ownership commonly safeguards that such assets are maintained. Cornides suggests that if such assets were available to everyone alike, for example in the form of common ownership, there would be a potential risk that everyone would make use of such goods without tending for their sustainability. Intellectual property, on the contrary, is non-contentious in that the protected knowledge is not limited in quantity and cannot be over-exploited. See thereto: Cornides J (n 73) 147.

Cornides uses the term ‘non-rivalrous’, which I have replaced with the more familiar term ‘non-contentious’.

Lastly, while it is submitted that the concept of common ownership may in reality not prove to be as bleak as suggested by Cornides, the example nevertheless indicates the substantial difference between property in limited tangible assets, and the IP in knowledge.

⁷⁷ Cornides J (n 73) 147.

⁷⁸ *ibid*.

patents, and thereby of IP, is not comparable to the protection of property in tangible assets.⁷⁹ In a letter to Isaac McPherson dated 13 August 1813, Jefferson wrote:

Inventions then cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from any body.⁸⁰

It can thus be suggested that, because of the considerable differences between IP and property in tangible assets, IP does not qualify as a human right based on the concept of the right to property alone. This interpretation is not unanimous, however, as notably the ECtHR proposes that the right to property under Article 1 of Protocol 1 to the ECHR is not limited to physical property, and thus implicitly includes the right to IP.⁸¹

Even when following the interpretation that IP fails to qualify as a human right under the right to property, IP may nevertheless constitute a human right, if it is expressly recognised as such by international human rights law. In this regard, while the UDHR does not directly refer to the term IP, Article 27(2) UDHR provides for the ‘protection of the moral and material interests resulting from any scientific, literary or artistic production’ of authors, which could be construed as a human right to IP.⁸² The protection interest of authors, however, is balanced against the public interest by Article 27(1) UDHR stipulating that everyone has the right ‘to share in scientific advancement and its benefits.’⁸³ Similarly worded, Article 15 ICESCR provides a right to the protection of the moral and material interests of authors of scientific, literary or artistic production in paragraph (1)(c) and a right of the public to share the benefits of scientific progress in paragraph (1)(b).⁸⁴ The CESCR further reaffirmed that IP serves a social function and should therefore ultimately be aimed at the promotion of human well-being.⁸⁵ Consequently, it must be acknowledged that the protection interests of

⁷⁹ *ibid* 150.

⁸⁰ Washington HA (ed), *The writings of Thomas Jefferson Vol. VI*. (Taylor & Maury 1855) 181.

⁸¹ Protocol 1 to the European Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, 20 March 1952) [Protocol 1 to the ECHR], Article 1; Brown AEL (n 55) 46; Cornides J (n 73) 140.

⁸² UDHR (n 10) Article 27 (2); cf. Drahos P (n 15) 358; Cornides J (n 73) 139.

⁸³ UDHR (n 10) Article 27 (1); cf. Drahos P (n 15) 358.

⁸⁴ International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) [ICESCR], Article 15(1)(b) and (c); cf. Drahos P (n 15) 358; Cornides J (n 73) 139.

⁸⁵ Committee on Economic, Social and Cultural Rights (CESCR), ‘Statement on Human Rights and Intellectual Property’ (14 December 2001) UN doc. E/C.12/2001/15, para 4.

authors and creators need to be adequately balanced against the public interest in the accessibility of intellectual products, so that IP rights need to be drafted in a way that respects the public right to access scientific advancements.⁸⁶ This limitation of IP rights, established within the doctrine of human rights law, is reflected by the objectives and principles of Articles 7 and 8 of the TRIPS Agreement for IP rights under private international law.⁸⁷ It follows that the rights of creators cannot be absolute, which indicates that states have a duty to implement a system of IP protection that strikes an adequate balance between private and public interests.⁸⁸

As can be seen, it can be suggested that the protection of certain forms of IP – namely scientific, literary and artistic productions – seemingly constitute a human right. It is argued by Brinkhof, however, that the term ‘scientific production’ is not synonymous with the term ‘invention’, as required by patent law.⁸⁹ As neither patents, nor inventions are explicitly referred to by human rights law, it may be suggested that not all types of IP are necessarily protected as human rights.⁹⁰ Brinkhof therefore proposes that there is no human right to patent protection.⁹¹ This view can be supported by acknowledging that patents under current international IP legislation fail to fulfil the requirement of Article 27(2) UDHR and Article 15(1)(c) ICESCR which aim at the protection of the authors of scientific production.⁹² Patents, in contrast, are regularly granted to persons who are not the original creator, such as the corporations or institutions that employ a successful inventor. A human right to IP is intended to ‘safeguard[] the personal link between authors and their creations’.⁹³ Therefore, the CESCR clarifies in General Comment No 17 that only the author or creator can be the

⁸⁶ Grosheide W, ‘General Introduction’ (n 71) 5; Matthews D, ‘Intellectual Property Rights, Human Rights and the Right to Health’ in Grosheide W (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar Publishing 2010) 121; Drahos P (n 15) 359.

⁸⁷ Grosheide W, ‘General Introduction’ (n 71) 15; See thereto: Chapter 2.4.2.3.

⁸⁸ cf. United Nations Economic and Social Council (ECOSOC), ‘The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights’ (27 June 2001) Un Doc E/CN.4/Sub.2/2001/13, paras 10-15; Matthews D, ‘Intellectual Property Rights, Human Rights and the Right to Health’ (n 86) 122.

⁸⁹ Brinkhof J, ‘On Patents and Human Rights’ in Grosheide W (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar Publishing 2010) 147-148.

⁹⁰ *ibid.*

⁹¹ *ibid.* 153.

⁹² Gordon WJ (n 69) 159-160.

⁹³ Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1 (c) of the Covenant)* (12 January 2006) UN Doc E/C.12/GC/17, para 2.

beneficiary of human rights protection under Article 15(1)(c) ICESCR.⁹⁴ Furthermore, as human rights are inalienable, they cannot be assigned to another person, because, as elaborated above in 3.1.1, they cannot be voluntarily surrendered.⁹⁵

It can be concluded that in the light of the current understanding of patents, there seems to be no human right to patent protection under international law, particularly when patents are held by corporations. Once a patent – or any other type of IP for that matter – has been granted, however, it may qualify as regular property and should then be protected by the human right to property, as provided for by Article 17 UDHR.⁹⁶ Article 17 stipulates the right of everyone to own property, and protects against arbitrary expropriation.⁹⁷ Like the protection of the rights of authors under international human rights law, the right to property is limited and can be restricted for public interests, at least in regional human rights treaties, for example under Article 1 of Protocol 1 to the ECHR and under Article 14 of the African Charter on Human and Peoples Rights.⁹⁸

While patents are not explicitly recognised by human rights law on an international level, they may still be regarded as human rights in a regional context. The Charter of Fundamental Rights of the European Union (EU Charter), for instance, not only provides a general right to property in Article 17(1), but furthermore explicitly stipulates in paragraph 2 that ‘Intellectual Property shall be protected.’⁹⁹ While it is noteworthy that again patents are not explicitly mentioned,¹⁰⁰ it must be acknowledged that by direct reference to the term IP, Article 17(2) of the EU Charter is more inclusive of different types of IP than both the UDHR and ICESCR. As the EU Charter does not provide any limitation to the term ‘intellectual property’, it can be suggested that, by conventional definition of IP, patents are included and thus protected as a human right under the EU Charter. While Article 17(2) gives little guidance on how IP shall be

⁹⁴ *ibid* paras 1-7; Gordon WJ (n 69) 160.

⁹⁵ CESCR, *General Comment No. 17* (n 93) para 1; Gordon WJ (n 69) 167; Woods K (n 2) 6.

⁹⁶ Brinkhof J (n 89) 153; Drahos P (n 15) 358.

⁹⁷ UDHR (n 10) Article 17.

⁹⁸ Protocol 1 to the ECHR (n 81) Article 1; African Charter on Human and People’s Rights (adopted 27 June 1981, entered into force 21 October 1986), Article 14; cf. Karamanian SL (n 16) 240; Drahos P (n 15) 359.

⁹⁹ Charter of Fundamental Rights of the European Union (ratified 7 December 2000) [EU Charter of Fundamental Rights], Article 17(2); cf. Brown AEL (n 55) 46; Cornides J (n 73) 140; Grosheide W, ‘General Introduction’ (n 71) 18-19; Matthews D, ‘Intellectual Property Rights, Human Rights and the Right to Health’ (n 86) 123.

¹⁰⁰ cf. Brinkhof J (n 89) 152.

protected, it has been elucidated, in particular by the drafting committee of the EU Charter, that the right to IP protection is subject to the conditions of the general right to property under Article 17(1).¹⁰¹ Hence, IP protection under the EU Charter has again to be balanced against the broader public interest.

In the final analysis, a convincing argument can be made proposing that the right to IP generally constitutes a human right, although it is not conclusively clarified whether this equally extends to patents, at least on a global level. At the same time, it can be submitted that conceptually IP does not belong to the category of fundamental human rights. For the purpose of this thesis, I propose that fundamental rights are those rights that are fundamental for human existence and well-being. It is therefore submitted that the protection of private monetary interests cannot be compared to the importance of fundamental human rights, protecting human life in dignity.¹⁰² The classification of rights as fundamental serves the purpose of emphasising specific supremely important values, thereby implying a hierarchical structure. It follows that in cases of conflict between fundamental and non-fundamental rights, fundamental rights should be prioritised. Consequently, if all human rights were awarded a fundamental status, the concept would become meaningless as no right could be prioritised.¹⁰³ It further follows that both the right to property and the right to IP cannot be regarded as absolute, as their protection is conditioned by the broader public interest, and aimed at contributing to the common good and welfare of society.¹⁰⁴ Thus, states are permitted not only to provide limitations to the protection of property in the public interest, but arguably further to adjust them to economic and social circumstances.¹⁰⁵

Additionally, it must be acknowledged that the protection of IP as a human right fundamentally differs from the extensive protection granted under international trade and IP law.¹⁰⁶ In this respect, the CESCR notes:

¹⁰¹ Brown AEL (n 55) 47; Matthews D, 'Intellectual Property Rights, Human Rights and the Right to Health' (n 86) 123.

¹⁰² cf. Drahos P (n 15) 366.

¹⁰³ Cornides J (n 73) 138.

¹⁰⁴ Karamanian SL (n 16) 242; Matthews D, 'Intellectual Property Rights, Human Rights and the Right to Health' (n 86) 122.

¹⁰⁵ Cornides J (n 73) 137; Drahos P (n 15) 360.

¹⁰⁶ cf. Brown AEL (n 55) 25; de Feyter K (n 3) 182; Gordon WJ (n 69) 157; Matthews D, 'Intellectual Property Rights, Human Rights and the Right to Health' (n 86) 124; CESCR, *General Comment No. 17* (n 93) para 2.

The fact that the human person is the central subject and primary beneficiary of human rights distinguishes human rights, including the right of authors to the moral and material interests in their works, from legal rights recognized in intellectual property systems. [...] Human rights are fundamental as they derive from the human person as such, whereas intellectual property rights derived from intellectual property systems are instrumental, in that they are a means by which States seek to provide incentives for inventiveness and creativity from which society benefits. [...] While intellectual property rights may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person. Whereas human rights are dedicated to assuring satisfactory standards of human welfare and well-being, intellectual property regimes, although they traditionally provide protection to individual authors and creators, are increasingly focused on protecting business and corporate interests and investments.¹⁰⁷ (*footnote omitted*)

It is therefore crucial to differentiate between the human rights attributes and the non-human rights attributes of IP.¹⁰⁸ In particular, it is suggested that the purpose of the human right to IP is not to secure a monetary right for creators, but rather to protect them from arbitrary governmental repression.¹⁰⁹ Thus, the human rights protection of IP cannot encompass the same private exclusive rights as granted to IP under international trade law. Otherwise, the construction of IP as a human right would entail the risk of elevating a right to a monopoly to a human rights standard, even where this is detrimental to society at large.¹¹⁰ According to Dreyfuss, the human rights recognition of IP should therefore not be furthered by providing ‘full control over the information that creative labor produces.’¹¹¹ Instead, human rights claims to IP must undoubtedly be limited by the human rights claims of the public at large.¹¹²

For the purpose of this thesis, it can be particularly emphasised that states should ensure that IP rights do not complicate the protection of the right to health, particularly with respect to unreasonably high pricing of patented products impeding the affordability of medicines, as further elaborated in chapter 4.2.2.¹¹³ As elaborated above, international instruments recognising IP as a human right provide for a balance

¹⁰⁷ CESCR, UN doc. E/C.12/2001/15 (n 85) para 6.

¹⁰⁸ Yu PK, ‘Ten Common Questions About Intellectual Property and Human Rights’ (2007) 23 Georgia State University Law Review 709, 738-739.

¹⁰⁹ Gordon WJ (n 69) 163.

¹¹⁰ cf. Grosheide W, ‘General Introduction’ (n 71) 30.

¹¹¹ Dreyfuss RC, ‘Patents and Human Rights: Where is the Paradox?’ in Grosheide W (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar Publishing 2010) 73.

¹¹² Gordon WJ (n 69) 159.

¹¹³ Brown AEL (n 55) 25.

between the rights of creators and the public interest, suggesting that private national and international IP laws need to be shaped in a way that pays due regard to this balance. As further elaborated in chapter 4.2.3, the current international patent regime, as established by the TRIPS Agreement, seemingly does not adequately reflect this balance, wherefore it must be called into question whether private international IP rights under the WTO system can be regarded as being in accordance with the requirements of the human right to IP.¹¹⁴

IP rights and other human rights, however, do not necessarily conflict and can, if appropriately applied, support each other.¹¹⁵ To this end, IP rights need to be balanced with essential other human rights, in order to reshape the understanding of their relationship towards one another.¹¹⁶ As a result, human rights could assist the designing of IP rights, and IP rights could then be utilised for the promotion of other human rights, by incentivising the development of vital public goods.¹¹⁷ Furthermore, when establishing a hierarchy between fundamental and non-fundamental human rights, IP as a human right could be more explicitly balanced with other human rights.¹¹⁸ Thereby, if adequately implemented, IP as a human right could, in theory, facilitate the identification of a hierarchy between the rights of creators and other human rights within human rights doctrine, which would eliminate the difficulty of establishing a hierarchy between different systems of international law, as discussed in the next section. For this approach to be effective, however, the concept of IP as a human right requires further authoritative interpretation.

3.1.3 The Relationship between IP Rights and Human Rights in Situations of Norm Conflict

Notwithstanding the recognition of IP as a human right, the question remains what the relationship, on the one hand, between international human rights law and IP regulated

¹¹⁴ cf. Grosheide W, 'General Introduction' (n 71) 23-24.

¹¹⁵ Brown AEL (n 55) 25.

¹¹⁶ cf. Matthews D, 'When Framing Meets Law: Using Human Rights as a Practical Instrument to Facilitate Access to Medicines in Developing Countries' (2011) 3 WIPO Journal 113, 119.

¹¹⁷ Drahos P (n 15) 367.

¹¹⁸ cf. Matthews D, 'Intellectual Property Rights, Human Rights and the Right to Health' (n 86) 122; Grosheide W, 'General Introduction' (n 71) 33.

under private international trade law, and on the other hand between IP as a human right and other human rights, and particularly the right to health, looks like. In order to explore this question, the following analysis considers the relevance of the fundamental status of the right to health, to identify whether a general superiority of this right can be established. The analysis then considers the inter-regime relationship between IP rights under trade law and human rights, before turning to the intra-regime relationship between IP as a human right and other human rights to identify whether a hierarchy between potentially conflicting norms exists within the doctrines of international law.

According to Woods, '[h]uman rights are especially weighty moral claims that generate corresponding duties, they are typically justified by appeal to universal human interests, they trump competing general claims.'¹¹⁹ It follows that human rights should only be impaired for exceptionally substantial objectives.¹²⁰ While it therefore seems entirely adequate to stipulate the existence of fundamental human values and rights applicable to everyone, it becomes more controversial to suggest that in general such rights are inalienable and incontrovertible.¹²¹

In contrast to domestic legal structures with hierarchical orders, international law is commonly considered as being of horizontal nature.¹²² Consequently, it is complex to identify a hierarchy between human rights and investment or trade law.¹²³ Conflicts can therefore arise when the adherence of one legal provision either, under a narrow definition unavoidably leads to, or, under a broad definition at least can lead to the breach or limitation of another legal norm.¹²⁴

¹¹⁹ Woods K (n 2) 16.

¹²⁰ Freeman M (n 3) 67.

¹²¹ O'Byrne DJ (n 5) 45.

¹²² de Wet E and Vidmar J, 'Introduction' in de Wet E and Vidmar J (eds), *Hierarchy in International Law: The Place of Human Rights* (OUP 2012) 1.

¹²³ Karamanian SL (n 16) 238.

¹²⁴ *ibid* 236-237; de Wet E and Vidmar J, 'Introduction' (n 122) 1-2.

3.1.3.1 Superior Norms, Absolute Rights, and the Fundamental Nature of the Right to Health

According to Vidmar, the prerequisite for the evolution of a hierarchical structure in international law, would be the ‘existence of an international value system’.¹²⁵ It may be submitted, however, that this value system is already provided for by the UDHR. Furthermore, the general existence of an international value system can be emphasised at least to the extent to which obligations *erga omnes* and *jus cogens* are recognised by international law.¹²⁶ Similarly, in accordance with its preamble, it can be suggested that the UN Charter emphasises the fundamental values of the international community.¹²⁷ When following the assumption that the UN Charter is at the core of the international constitutional order, it can arguably be proposed that the UN Charter establishes the priority of human rights.¹²⁸ This is supported by Article 103 of the UN Charter which stipulates that ‘[i]n the event of a conflict between the obligations of the Members of the United Nations under the present Charter and their obligations under any other international agreement, their obligations under the present Charter shall prevail.’¹²⁹ Thus, Article 103 essentially grants the UN Charter hierarchically superiority in international law.¹³⁰

Article 103 becomes particularly relevant for this thesis when read in conjunction with Article 55(b) of the UN Charter, which, *inter alia*, stipulates the promotion of the protection of human health.¹³¹ As a result, it can be proposed that the UN Charter may elevate the protection of human health to a superior level in situations of norm conflict under international law. A dissenting opinion, however, may suggest that Article 103 of the UN Charter is not designed to establish a general hierarchy in international law.¹³² This view can be supported when accepting that, according to Vidmar, ‘Article

¹²⁵ Vidmar J, ‘Norm Conflicts and Hierarchy in International Law: Towards a Vertical International Legal System?’ in de Wet E and Vidmar J (eds), *Hierarchy in International Law: The Place of Human Rights* (OUP 2012) 14.

¹²⁶ *ibid.*

¹²⁷ *ibid.* 16.

¹²⁸ Cohn M, ‘The World Trade Organization: Elevating Property Interests Above Human Rights’ (2001) 29 *Ga J Int’l & Comp L* 427, 439; McCorquodale R, ‘An Inclusive International Legal System’ (2004) 17 *Leiden Journal of International Law* 477, 478.

¹²⁹ The Charter of the United Nations (signed 26 June 1945, entered into force 24 October 1945) [UN Charter], Article 103.

¹³⁰ Vidmar J, ‘Norm Conflicts and Hierarchy in International Law’ (n 125) 18.

¹³¹ UN Charter (n 129) Article 55(b).

¹³² de Wet E and Vidmar J, ‘Conclusions’ (n 17) 302.

103 does not invalidate an obligation contradicting the Charter, but rather suspends the duty of a state to fulfil such an obligation.’¹³³ Similarly, while the UN Charter reinforces the superior importance of the protection of human health, it must be acknowledged that Article 103 does not elevate specific human rights provisions to a superior status, but only the obligations of the UN Charter.¹³⁴ It follows that because Art 55(b) refrains from clearly identifying specific obligations other than the general promotion of the protection of human health, a legal superiority of the human right to health under international law cannot be derived from the UN Charter *per se*.

A superiority of the right to health may nevertheless be established in recognition of its classification as a fundamental human right, as suggested in chapter 1.2. For this, it must be scrutinised whether, due to its fundamental status, the right to health constitutes an absolute right. In that case, the right to health would be of legal superiority, as inherently, derogations from absolute rights cannot be justified.¹³⁵ The absoluteness of the right to health could potentially be established, if it was recognised as a norm of *jus cogens* or as an obligation *erga omnes*. Such norms are international principles from which no derogation is permitted, which, according to Ragazzi, do not merely derive their binding nature from states recognising their validity, but more fundamentally ‘because nobody can claim special exemptions from moral absolutes.’¹³⁶ In this regard, Article 53 VCLT provides that treaties that conflict with such peremptory norms of international law are automatically void.¹³⁷ Conceivably, the prohibition of gross and systematic violations of human rights may be considered as a peremptory principle.¹³⁸ According to de Feyter, the patent regime provided by the TRIPS agreement may potentially lead to such gross and systematic violations of the human right to health when extensive patent protection prevents the accessibility of essential medicines.¹³⁹

¹³³ Vidmar J, ‘Norm Conflicts and Hierarchy in International Law’ (n 125) 19.

¹³⁴ *ibid.*

¹³⁵ cf. de Wet E and Vidmar J, ‘Conclusions’ (n 17) 301; van der Wilt H, ‘On the Hierarchy between Extradition and Human Rights’ in de Wet E and Vidmar J (eds), *Hierarchy in International Law: The Place of Human Rights* (OUP 2012) 173.

¹³⁶ cf. VCLT (n 28) Article 53; Ragazzi M, *The Concept of International Obligations Erga Omnes* (OUP 2000) 183.

¹³⁷ VCLT (n 28) Article 53.

¹³⁸ de Feyter K (n 3) 183.

¹³⁹ *ibid* 183-184.

Most peremptory norms belong to the field of human rights, which may suggest that certain human rights enjoy superiority within international law.¹⁴⁰ The identification of such norms, however, is rather difficult and broad interpretations are regularly rejected by the courts.¹⁴¹ After all, only a very limited number of indispensable rights – including the prohibition of torture, the prohibition of genocide, the prohibition of slavery, and the prohibition of racial discrimination – have been widely acknowledged as *jus cogens* and obligations *erga omnes*,¹⁴² whereas the argument that the right to health falls within these categories would be difficult to uphold.¹⁴³ The practical relevance of peremptory norms in consideration of trade law and human rights, thus appears to be rather limited.¹⁴⁴

Ultimately, the biggest obstacle for proposing the absoluteness of the right to health may be created by the ICESCR itself. The fact that the right to health is subject to progressive realisation under Article 2(1) ICESCR indicates that, at least to a certain extent, derogations are permissible. It is therefore concluded that the fundamental nature of the right to health does not imply its recognition as absolute, so that a general superiority of the right to health in international law cannot be established.

3.1.3.2 The Inter-Regime Relationship between IP Rights under Trade Law and Human Rights

The general binding nature of international human rights law suggests that normative conflicts may emerge when states enter into other legally binding treaties – for instance under international trade law – which may entail provisions that undermine the spirit of human rights.¹⁴⁵ While, as discussed in chapter 1.2.1.3, the CESCR regards the signing up to treaties that restrict a state's capability of complying with relevant human rights obligations as a potential violation of the ICESCR,¹⁴⁶ in reality international trade law frequently restricts governmental room for manoeuvre. Similarly, the obligation of international assistance is frequently repeated throughout the ICESCR

¹⁴⁰ de Wet E and Vidmar J, 'Introduction' (n 122) 3.

¹⁴¹ *ibid.*

¹⁴² Vidmar J, 'Norm Conflicts and Hierarchy in International Law' (n 125) 36.

¹⁴³ For further understanding on the concepts of *jus cogens* and obligations *erga omnes*, see: Vidmar J, 'Norm Conflicts and Hierarchy in International Law' (n 125) 13-41.

¹⁴⁴ cf. de Wet E and Vidmar J, 'Conclusions' (n 17) 301.

¹⁴⁵ de Feyter K (n 3) 23.

¹⁴⁶ cf. *ibid* 182.

and was interpreted as including the obligation of state parties to abstain from any policies that adversely impact on the protection of economic and social human right in other countries.¹⁴⁷ Under the ICESCR, limitations of economic, social, and cultural rights are only permitted ‘for the purpose of promoting the general welfare in a democratic society’,¹⁴⁸ not, however, for the mere promotion of private economic interests.¹⁴⁹ In this regard, while reaffirming the right of authors under Article 27(2) UDHR and Article 15(1)(c) ICESCR, the UN Sub-Commission on the Protection and Promotion of Human Rights declared in 2001 that ‘the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights’.¹⁵⁰ The Sub-Commission therefore proceeded to remind ‘all Governments of the primacy of human rights obligations over economic policies and agreements’.¹⁵¹ Consequently, the ratification of WTO or FTA provisions that interfere with human rights obligations could conceivably constitute a violation of the ICESCR. While it thus seems that human rights are considered as being more essential than private IP rights, the Sub-Commission further recognises the important social function of IP of encouraging innovation and creativity.¹⁵² The question of whether IP rights provided under international trade law actually stand in contradiction to economic and social human rights, is thus to be determined in light of the extent to which international IP law is capable of adequately promoting the general welfare of the public, as further elaborated in chapters 4.2 and 4.3. From a human rights point of view,¹⁵³ it therefore

¹⁴⁷ *ibid* 58.

¹⁴⁸ ICESCR (n 84) Article 4.

¹⁴⁹ de Feyter K (n 3) 181.

¹⁵⁰ Office of the United Nations High Commissioner for Human Rights (OHCHR), ‘Intellectual Property Rights and Human Rights, Sub-Commission on Human Rights Resolution 2000/7’ (17 August 2000) UN Doc E/CN.4/SUB.2/RES/2000/7, para 2.

¹⁵¹ *ibid* para 3.

¹⁵² Brown AEL (n 55) 22-25.

¹⁵³ This human rights point of view may be contested by the so-called ‘market-friendly approach’ to human rights. This approach favours civil and political human rights while questioning the validity of economic and social human rights. Furthermore, the market friendly approach suggests that human rights are not to be seen as being of primary relevance in the international legal order. Instead, this concept proposes that human rights can only be legitimate if they do not interfere with the functionality of the free market. According to the market-friendly approach, solutions to human rights and international trade discrepancies therefore need to be found within the international trade regime. This notion, however, stands in stark contrast to the very purpose of human rights, as particularly economic and social human rights are directly aimed at the protection of exactly those peoples who are most vulnerable to fall victim to the adverse effects of the free market economy. Consequently, it is essential for economic and social rights to be effective that a certain priority is granted to human rights for challenging injustices brought about by the free market economy, in order to protect those peoples who are mainly exposed to its adverse effects but prevented from enjoying its benefits. For this reason, the market friendly approach is rejected

seems crucial, for IP rights to be accepted and justified, that human rights are duly considered as determining limitations of IP protection.¹⁵⁴

The WTO, however, arguably sets out rules that are designed to restrict the public policy options of states by enforcing regulations that expand the private power of international economic actors.¹⁵⁵ While the General Agreement on Tariffs and Trade (GATT) recognised potential exceptions to free trade rules for, inter alia, the protection of public morals, and human life and health, the WTO has never explicitly elaborated the relationship between its trade rules and human rights.¹⁵⁶ The objectives and exceptions of the TRIPS Agreement, nevertheless, indicate the WTO's acknowledgement of the importance of striking an adequate balance between IP and the public interest,¹⁵⁷ particularly the interest in knowledge that directly impacts on human life and health. Consequently, the TRIPS Agreement should be interpreted and implemented in a way that pays due regard to human rights, and particularly the right to health, before conflicts arise.¹⁵⁸ When further considering the Doha Declaration's reaffirmation of the authority of governments to protect public health, as elaborated in chapter 2.3, the existence of a certain superiority of the right to health over IP rights within the WTO system may be implied, as the Doha Declaration constitutes a document of both trade law and human rights, which implicitly recognises the significance of the rights to life and health.¹⁵⁹ Thereby, the Doha Declaration may be regarded as the basis for the acknowledgement of human rights within the international IP regime.¹⁶⁰

It must be noted, however, that both the TRIPS Agreement and the Doha Declaration avoid any direct reference to human rights.¹⁶¹ It therefore seems that while the WTO recognises the importance of certain human rights elements, human rights are not generally accepted as a justification for the disregard of international trade obligations.

by this thesis as a valid argument elaborating on the legal standing of human rights. For further elaboration on the market friendly approach see: de Feyter K (n 3) 28-30 and 179.

¹⁵⁴ Van Overwalle G, 'Human Rights' Limitations in Patent Law' in Grosheide W (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar Publishing 2010) 237.

¹⁵⁵ de Feyter K (n 3) 16.

¹⁵⁶ Freeman M (n 3) 188.

¹⁵⁷ cf. de Feyter K (n 3) 178.

¹⁵⁸ cf. *ibid* 179.

¹⁵⁹ Abbott FM, 'The "Rule of Reason" and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPS' in Cottier T, Pauwelyn J, and Bonanomi EB (eds), *Human Rights and International Trade* (OUP 2005) 279-283.

¹⁶⁰ Ziegler AR and Boie B (n 1) 297.

¹⁶¹ Abbott FM (n 159) 283; de Feyter K (n 3) 181.

Similarly, as indicated in chapter 2.5, a number of FTAs implement objectives or side letters that, without making any direct reference to human rights, seem to highlight the importance of certain public rights, commonly including the protection of public health. The mode of expression used in those FTAs, however, appears to be directed at promoting trade objectives, while avoiding conflicts by maintaining the authority of states to regulate in the public interest, and not at establishing a general superiority of human rights concerns.¹⁶²

It is important to realise that the avoidance of human rights language in trade agreements tends to hamper the observance of human rights in trade related conflict resolutions. This is due to the fact that the prioritisation of certain rights is subject to the body dealing with a specific dispute.¹⁶³ To put it differently, courts and tribunals are required to act within their mandate, meaning that human rights courts are instructed to follow applicable human rights treaties, potentially prioritising human rights law over trade rules, while trade tribunals focus on trade agreements, and prioritise trade concerns.¹⁶⁴ Thus, without an explicit reference to human rights in relevant trade agreements, there is hardly an incentive for trade tribunals to elaborate on human rights issues in trade disputes. It can therefore be suggested that in international law separate treaty systems generally tend to operate parallel to each other without significant interdependence.¹⁶⁵

Consequently, as the WTO DSU ‘serves to preserve the rights and obligations of members under the covered agreements,’ and as its rulings ‘cannot add to or diminish the rights and obligations provided in the covered agreements’,¹⁶⁶ the DSU is unlikely to defer trade law in order to prioritise human rights obligations which are not covered by WTO treaties.¹⁶⁷ Nevertheless, according to Article 31(3)(c) VCLT, ‘[a]ny relevant rules of international law applicable in the relations between the parties’ shall be taken into account, indicating that human rights treaties applicable to either of the disputing

¹⁶² Karamanian SL (n 16) 245-246.

¹⁶³ *ibid* 238.

¹⁶⁴ *ibid*.

¹⁶⁵ Ziegler AR and Boie B (n 1) 276.

¹⁶⁶ Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 of the Marrakesh Agreement Establishing the World Trade Organization (signed 15 April 1994, entered into force 1 January 1995) [WTO DSU], Article 3(2).

¹⁶⁷ de Feyter K (n 3) 185.

parties should be given due consideration in WTO and FTA disputes.¹⁶⁸ In 1996, the WTO Appellate Body acknowledged the applicability of ‘customary rules of interpretation of public international law’ to WTO disputes, stipulating that WTO law ‘is not to be read in clinical isolation from public international law.’¹⁶⁹ The Appellate Body’s disinclination to separate WTO law from other systems of international law, implies that the WTO acknowledges the significance of recognising public international law, including human rights concerns, when addressing trade disputes.¹⁷⁰

Furthermore, Professor Monica Pinto, in her role as expert witness to the *Impregilo v Argentina* case, pointed out that arbitral tribunals may not ‘overlook the fact that one of the parties’ to trade and investment disputes is a sovereign state that ‘cannot set aside the issues relating to public law affected by such negotiations,’ which includes human rights.¹⁷¹ Additionally, in light of the repeated affirmation of the right of states to make exceptions to trade rules for the protection of public health, it must be acknowledged that the WTO DSU is required to give meaningful effect to this right in its rulings.¹⁷² In effect, it may be suggested that this acknowledgement grants the right to health a certain priority within the WTO’s constitutional order.¹⁷³

Be that as it may, trade tribunals that actually do rule in favour of protecting human rights still tend to avoid making direct references to human rights law, instead cautiously founding their decisions on trade law objectives and principles.¹⁷⁴

¹⁶⁸ VCLT (n 28) Article 31(3)(c).

The application of the VCLT in such disputes, however, is not entirely unproblematic, as the VCLT is mainly designed to provide guidance on intra-regime conflicts, by, inter alia, elaborating the relationship between *lex generalis* and *lex specialis* within a treaty regime. Inter-regime conflicts, however, have received little attention in the VCLT. Conflicts between trade law and human rights arise between two separate, specialised treaty regimes, both of which constitute *lex specialis*. The VCLT does not address any hierarchical order between different types of *lex specialis*. Be that as it may, Article 31(3)(c) VCLT explicitly refers to ‘any relevant rules of international law’, thereby stepping away from purely intra-regime considerations. There is no further guidance, however, on how those relevant rules of international law need to be taken into account. Thereby, it must be concluded that the VCLT does not intend to establish a defined hierarchy between different treaty regimes, but rather aims at reaffirming the existence and importance of different bodies of international law. See thereto: de Wet E and Vidmar J, ‘Conclusions’ (n 17) 305-306; Ziegler AR and Boie B (n 1) 290.

¹⁶⁹ WTO Appellate Body Report, *United States - Standards for Reformulated and Conventional Gasoline* (29 April 1996) WT/DS2/AB/R, page 17.

¹⁷⁰ Ziegler AR and Boie B (n 1) 275.

¹⁷¹ International Centre for Settlement of Investment Disputes (ICSID), *Impregilo S.p.A. v Argentine Republic* (5 January 2010) ICSID Case No ARB/07/17, Supplemental Expert Report by Professor Monica Pinto, para 7, as quoted in Karamanian SL (n 16) 259.

¹⁷² Abbott FM (n 159) 284.

¹⁷³ cf. *ibid* 297.

¹⁷⁴ cf. Karamanian SL (n 16) 263.

According to Ziegler, it may therefore be suggested that in international legal proceedings there is a general tendency of tribunals to avoid directly addressing the controversial question of identifying treaty overarching superior norms.¹⁷⁵ Consequently, international case law does not provide precedents to establish an unanimous hierarchy between trade law and human rights.¹⁷⁶

It is noteworthy, however, that trade disputes are not only heard in international proceedings, and that national courts can interpret the domestically implemented TRIPS and FTA provisions in a manner supportive of human rights, particularly where human rights are recognised by national constitutions, which may grant them superiority within a national legal order.¹⁷⁷ As the ensuing rulings would then potentially require governments to disregard international trade obligations in order to comply with their human rights obligations, resulting state action would likely be challenged under international arbitration. In this regard, FTAs have extensively contributed to shifting the balance towards a factual prioritisation of trade obligations, as modern trade agreements require states to pay compensation to private actors for executing policy measures that reduce the value of investments, even where such policies are aimed at the protection of human rights.¹⁷⁸ Furthermore, the unusual strong enforcement and harsh sanctions for non-compliance provided for by international trade law ensure its practical efficacy, while major parts of human rights law remain paper rules due to its comparatively weak enforcement mechanisms.¹⁷⁹ As a result, this can lead to a ‘regulatory chill’ where in particular developing countries become reluctant to adopt public policies aimed at the protection of human rights, if there is a risk of facing expensive trade litigation and potential sanctions.¹⁸⁰

Additionally, it can be observed that the poor and marginalised in developing countries frequently lack adequate access to legal representation due to the high costs involved.¹⁸¹ In combination with the fact that powerful corporations, with sophisticated legal representation, are frequently parties to disputes involving economic and social human rights, it can be anticipated that human rights come out on

¹⁷⁵ *ibid*; Ziegler AR and Boie B (n 1) 298.

¹⁷⁶ Karamanian SL (n 16) 269.

¹⁷⁷ For examples see: de Feyter K (n 3) 187.

¹⁷⁸ Freeman M (n 3) 188.

¹⁷⁹ de Feyter K (n 3) 33; Drahos P (n 15) 356.

¹⁸⁰ Freeman M (n 3) 188; Stuhldreier M (n 67) 189-195. See also: chapter 2.4.1.

¹⁸¹ de Feyter K (n 3) 60.

the short end.¹⁸² It can thus be concluded that while from a purely doctrinal view there is no prioritisation of trade concerns in international law, the extensive power of the WTO and subsequent FTAs seem to elevate trade law to a factually superior level.

3.1.3.3 The Intra-Regime Relationship between IP as a Human Right and other Human Rights

In addition to inter-regime conflicts, there is a further possibility that, in respect of the human right to IP, intra-regime conflicts between IP and other human rights may occur within the human rights doctrine.¹⁸³ In such situations, it may be adequate to allocate different importance to individual human rights, based on their relevance for protecting human dignity.¹⁸⁴ Stipulating such a distinction, however, would be difficult to justify within the international human rights framework.¹⁸⁵ According to Freeman, a better solution to this problem may therefore be established by respecting all rights alike, and in cases of unavoidable collision distributing sacrifices evenly.¹⁸⁶ Where one right, however, directly protects human life and health, while another right mainly concerns monetary interests, such balanced sacrifices seem to contradict the very fundamental value of human dignity.

A different approach to addressing conflicting human rights would be to follow the concept of human rights being grounded in human agency. Under this notion, priority is conceded to rights of higher significance for human agency, which interrelates with human dignity.¹⁸⁷ Consequently, certain basic rights, i.e. rights addressing essential objectives, would need to be identified: the protection of which would justify disregarding other less important rights, but not *vice versa*.¹⁸⁸ This conceptualisation of basic rights, however, is highly controversial and not universally accepted.¹⁸⁹ Nevertheless, rights that protect human life in dignity seem to enjoy an elevated fundamental status.¹⁹⁰ Under European law, for example, the ECJ has confirmed that

¹⁸² *ibid.*

¹⁸³ de Wet E and Vidmar J, 'Introduction' (n 122) 2.

¹⁸⁴ *cf.* Freeman M (n 3) 83.

¹⁸⁵ *ibid.*

¹⁸⁶ *ibid.*

¹⁸⁷ *ibid.*

¹⁸⁸ *ibid* 83-84; Brown AEL (n 55) 48.

¹⁸⁹ Freeman M (n 3) 84.

¹⁹⁰ *ibid* 179.

human dignity was a fundamental value against which the validity of other rights needs to be justified.¹⁹¹ More explicitly, the Adelphi Charter on Creativity, Innovation and Intellectual Property stipulates that IP laws ‘must serve, and never overturn, the basic human rights to health, education, employment and cultural life.’¹⁹² Apart from the recognition of a limited number of peremptory norms of international law, as elaborated above in 3.1.3.1, however, it seems that the question of an intra-regime hierarchy within the human rights doctrine is not yet conclusively established. The concepts of human dignity and human agency will be revisited below in 3.2.1.2, scrutinising moral reasons that may suggest the superiority of certain human rights above other less-essential rights.

3.1.4 Conclusion

In the final analysis, the preceding sections of this chapter can be summarised to answer Research Question 1:

What is the relationship between international human rights law and international IP/trade law?

In essence, the present analysis established that international law is divided into functionally detached treaty regimes that frequently omit providing a distinctive elaboration of their relationship towards one another.¹⁹³ Furthermore, judicial bodies are commonly reluctant to explicitly address the controversial issues surrounding the identification of hierarchical structures between conflicting norms of different treaty regimes.¹⁹⁴ It can therefore be concluded that from a purely legal point of view there is no consistently uniform rule of hierarchy between human rights and IP/trade law

¹⁹¹ Brown AEL (n 55) 72-73.

¹⁹² Royal Society of Arts, Manufactures and Commerce (RSA), ‘Adelphi Charter on Creativity, Innovation and Intellectual Property’ (launched 13 October 2005) in RSA (ed), *Promoting Innovation and Rewarding Creativity: A Balanced Intellectual Property Framework for the Digital Age* (RSA 2006) 4, Principle 2.

The Adelphi Charter of 13 October 2005, was drafted by an international commission consisting, inter alia, of politicians, scientists, lawyers, economists, and academics. The Charter provides guidance on how challenges of IP policies in the twenty-first century can be tackled in a fair and user-friendly way. See thereto: Brown AEL (n 55) 22-23; NOEMA, ‘Adelphi Charter on Creativity, Innovation and Intellectual Property’ <<https://noemalab.eu/memo/adelphi-charter-on-creativity-innovation-and-intellectual-property/>> accessed 23 May 2019.

¹⁹³ cf. Ziegler AR and Boie B (n 1) 299.

¹⁹⁴ de Wet E and Vidmar J, ‘Conclusions’ (n 17) 309.

under international law.¹⁹⁵ Instead, according to the principle of harmonious interpretation, as indicated by Article 31(3)(c) VCLT, different treaty regimes should be harmonised by avoiding conflicts through balanced interpretations.¹⁹⁶ This, however, can be detrimental for the protection of human rights where restrictions adversely impact on human dignity.¹⁹⁷ The extensive, strong enforcement mechanisms provided for international trade law further jeopardise the adequate observance of comparatively more weakly enforced human rights, so that human rights are destined to lose out in situations of conflict. It can therefore be observed that the non-existence of a prioritisation of human rights is debilitating to their very purpose.

3.2 The Concept of Morality and its Applicability to Norm Conflicts in International Law

In order to analyse the justification of the international patent regime in chapter 4, it is essential to establish the parameters against which this justification can be scrutinised. In this regard, the preceding analysis established that currently there exists no clearly defined hierarchy in international law which would suggest the superiority of either IP or human rights law in cases of norm conflict. Therefore, the following analysis steps aside from purely legal considerations and takes account of moral values to establish whether there are ethical reasons that suggest the superiority of either of the legal regimes, particularly in respect of the fundamental status of the right to health.

As shown above, IP rights are designed to fulfil the objective of serving the public benefit by promoting progress and development.¹⁹⁸ The right to intellectual property, similarly to all property rights, therefore does not constitute an end in itself. As can be derived from the various limitations imposed on property rights, IP rights are subordinated to the public interest and serve the purpose of contributing to the achievement of higher societal aims, including the protection of human life and human

¹⁹⁵ cf. *ibid* 301 and 309; Cornides J (n 73) 167.

¹⁹⁶ cf. de Wet E and Vidmar J, 'Conclusions' (n 17) 309.

¹⁹⁷ cf. *ibid*; Freeman M (n 3) 83.

¹⁹⁸ Cornides J (n 73) 158.

dignity.¹⁹⁹ It is therefore crucial for human rights to provide external limitations to the application of IP rights.²⁰⁰

Without delving into the scrutiny of the justification for the state, it is submitted here that the general purpose of states is to ensure that societal needs are fulfilled. The rights of individuals must therefore be considered in a societal context and adequate limitations should be applied to safeguard the public benefit.²⁰¹ Correspondingly, Ostergard argues that certain human rights should stand above other (human) rights, and that in particular, human rights that protect human well-being should have priority over IP rights.²⁰² As the human right to (intellectual) property can be restricted for the promotion of fundamental public interests, the right to property, according to Grosheide, does not constitute a fundamental right.²⁰³

The aim of the following section is to establish that – unlike intellectual property rights – the protection of human life and human health, and the concomitant human rights, serve fundamental human interests, not only justifying limitations to property rights, but being hierarchically superior to less-essential rights. In the light of the prior discussion that international law does not establish a clear hierarchy between these fundamental public interests and trade law, the following analysis needs to be founded on considerations other than purely legal reasoning and black-letter law. Therefore, the identification of a potential hierarchical superiority of specific rights will be based on ethical philosophy and moral principles. In particular, the analysis follows the concept that certain human rights are distinguished from less-essential rights not by law, but by the very nature of the fundamental value of human dignity.²⁰⁴

In order to establish whether moral values and the concept of human dignity justify the hierarchical superiority of certain human rights, it is of crucial importance to consider further the exact scope and meaning of the concepts of morality and human dignity. The following sub-chapter 3.2.1 does this by providing a definition of morality, and the concepts of human agency and human dignity, before considering ethics as moral philosophies, and the possibility of identifying a universally valid

¹⁹⁹ *ibid* 143, 155, and 159.

²⁰⁰ Gordon WJ (n 69) 177.

²⁰¹ Cornides J (n 73) 166-167.

²⁰² Ostergard RL, 'Intellectual Property: A Universal Human Right?' (1999) 21 *Human Rights Quarterly* 156, 175-177.

²⁰³ Grosheide W, 'General Introduction' (n 71) 20.

²⁰⁴ *cf.* Cornides J (n 73) 137; Freeman M (n 3) 69.

supreme moral principle. Subsequently, sub-chapter 3.2.2 applies the concept of human dignity in the light of Kant's 'Categorical Imperative' and Gewirth's 'Principle of Generic Consistency', aiming to identify a valid moral principle which equates moral goodness with the promotion of human well-being as a basic right. Ultimately, sub-chapter 3.2.3 will provide an answer to Research Question 2:

Are there valid moral principles that can be utilised to justify the prioritisation of the right to health over contradictory provisions of international trade law and patent law?

3.2.1 The Concept of Morality

3.2.1.1 Definition of Morality

According to the Oxford Dictionary, morality is defined as: 'Principles concerning the distinction between right and wrong or good and bad behaviour.'²⁰⁵ Thus morality can be both (a) '[a] particular system of values and principles of conduct', and (b) '[t]he extent to which an action is right or wrong.'²⁰⁶ Morality is not only concerned with human actions as such, but further considers the motives and reasons behind such actions.²⁰⁷ Morality thus evaluates the goodness of conduct, as well as the goodness of character.²⁰⁸ In particular, two main aspects have been utilised by philosophers aiming to define the meaning of morality. The first aspect quite simply holds that the concept of morality strives to achieve well-being and to avoid ill-being.²⁰⁹ The second aspect emphasises an egalitarian and universalist nature of morality, suggesting that moral rules are those that promote the good of everyone.²¹⁰ Moral conduct can be contrasted either with (a) non-moral conduct, i.e. actions that are not of a moral nature, or (b) with immoral conduct, i.e. actions that directly contradict valid moral principles.²¹¹

²⁰⁵ Oxford Living Dictionary, 'Morality' <<https://en.oxforddictionaries.com/definition/morality>> accessed 23 May 2019.

²⁰⁶ *ibid.*

²⁰⁷ Taylor PW, 'What Is Morality? Introduction' in Taylor PW (ed), *Problems of Moral Philosophy: An Introduction to Ethics* (2nd edn, Dickenson Publishing Company 1972) 3.

²⁰⁸ *ibid.*

²⁰⁹ Gewirth A, *Reason and Morality* (University of Chicago Press 1978) 9.

²¹⁰ *ibid.*

²¹¹ Taylor PW, 'What Is Morality? Introduction' (n 207) 5.

Morality, as a rule of conduct, prescribes guidelines for everyone's conduct that take precedence over all other motivations, such as self-interest, by determining how anyone ought to act in certain circumstances.²¹² Further, morality can be a mode of evaluation, establishing whether a certain action is good or bad.²¹³ While there are a variety of meanings attributed to the concept of morality, according to Gewirth, a certain core meaning can be constructed:

‘[M]orality is a set of categorically obligatory requirements for action that are addressed at least in part to every actual or prospective agent, and that are concerned with furthering the interests, *especially the most important interests*, of persons or recipients other than or in addition to the agent or the speaker. The requirements are categorically binding in that compliance with them *is mandatory for the conduct of every person* to whom they are addressed *regardless of whether he wants to accept them or their results*, and *regardless also of the requirements of any other institutions such as law or etiquette*, whose obligatoriness may itself be doubtful or variable.’²¹⁴ (*emphasis added*)

It can thereby be determined that the protection of the most important human interests imposes binding moral obligations on everyone, irrespective of whether one personally accepts the moral principle. The weight of such a moral principle, further, elevates the requirement to adhere to it above contradictory legal provisions. According to natural law theory, for example, a law is only justified if it is rationally moral and for the benefit of the common good.²¹⁵ The purpose of law is therefore to be seen in the rendition of moral obligations.²¹⁶ It is on this assumption that the following analysis seeks to identify a moral principle that justifies the superiority of certain human rights in the legal hierarchy.

²¹² *ibid* 3; Gewirth A, *Reason and Morality* (n 209) 1.

²¹³ Taylor PW, ‘What Is Morality? Introduction’ (n 207) 3.

²¹⁴ Gewirth A, *Reason and Morality* (n 209) 1.

²¹⁵ Ehrenberg KM, *The Functions of Law* (OUP 2016) 69.

²¹⁶ *ibid* 82.

A strong reading of the natural law theory rejects laws that do not fulfil this purpose, denoting them as not truly legal, i.e. not-law. This radical view, however, is criticised by legal positivists, highlighting the inconsistency in the claim that unjust laws are not-law. As a consequence, a weak reading of the natural law theory evolved, simply suggesting that unjust laws are merely defective. While this weak reading has similarities with legal positivism, a major difference can be identified whereby legal positivists hold that defective laws are nevertheless legally valid, while natural law theorists do not support this view. See thereto: Ehrenberg KM (n 215) 69-71 and 80-81.

3.2.1.2 Definition of Human Agency and Human Dignity

The definition of the exact scope of these moral obligations for the protection of the most important human interests requires the identification of what those interests are. In this respect, the following analysis elaborates on the concepts of human agency and human dignity, which may potentially constitute the most essential human values because of their fundamental importance for realising a meaningful human existence.

Human agency is the capability of human beings to act independently, making voluntary choices according to their free will.²¹⁷ To that end, human agents have generic needs, i.e. requirements that need to be fulfilled for agents to successfully act towards a purpose.²¹⁸ According to Gewirth, those generic needs, also referred to as generic goods, consist of three types of goods: non-subtractive goods, additive goods, and basic goods.²¹⁹ Non-subtractive and additive goods constitute second-order goods in that they are relative to an individual's status quo of possessions and opinions.²²⁰ Non-subtractive goods are goods that retain an individual agent's current standard, while additive goods are required for raising this standard, i.e. for achieving a higher level of purpose-fulfilment.²²¹ While the scope of second-order goods varies between different groups and persons, basic goods can be regarded as first-order goods as they have the same relevance for all human agents.²²² This can be illustrated, for example, by reference to the right to food, on the one hand, which protects a basic good in that nutrition is a vital prerequisite for the existence of all humans alike, while a right to paid holidays, on the other hand, addresses a second order good in that it increases living standards without being an essential human need.²²³ In fact, basic goods 'constitute the general necessary preconditions of action'.²²⁴ They comprise, inter alia, physical and mental capacities, including an agent's freedom, life itself, and physical integrity.²²⁵ The notion of physical integrity stipulates that the basic goods further include the necessary means for the preservation of life, i.e. food, clothing, shelter,

²¹⁷ cf. Gewirth A, *Reason and Morality* (n 209) 48-54.

²¹⁸ *ibid* 62-65; Beylveld D and Brownsword R, *Human Dignity in Bioethics and Biolaw* (OUP 2001) 70.

²¹⁹ Gewirth A, *Reason and Morality* (n 209) 54.

²²⁰ *ibid* 55.

²²¹ *ibid* 54-56.

²²² Gewirth A, *Reason and Morality* (n 209) 54.

²²³ Freeman M (n 3) 83.

²²⁴ Gewirth A, *Reason and Morality* (n 209) 54.

²²⁵ *ibid* 54 and 63.

health and the like.²²⁶ As the basic goods – which summarised comprise of freedom and basic well-being – are the fundamental requirements for human agency, they can also be considered as necessary goods, or basic needs.²²⁷

This is where, for the purpose of this thesis, a connection between human agency and human dignity can be drawn. A major obstacle with the consideration of human dignity, is that the very notion of dignity is vague and ambiguous.²²⁸ In essence, however, two concepts of dignity can be identified. In the historical context, dignity was commonly regarded as being attached to a certain role or position, for example someone holding a particular office. Further, dignity was connected to the social order, and persons of higher standing, such as members of the nobility, were considered to attract a higher degree of dignity.²²⁹ This concept can therefore be labelled as hierarchical dignity.²³⁰ Conversely, the contemporary moral concept of dignity, i.e. human dignity, recognises the inherently equal worth of all human beings.²³¹ The dignity of the human person is inalienable, or, as illustrated by Article 1(1) of the German Constitution, inviolable, and applies equally to everyone simply as an inherent feature of being human.²³² Reference to human dignity can further be found in all three documents of the International Bill of Rights, with both the ICESCR and the ICCPR stipulating that human rights ‘derive from the inherent dignity of the human person’.²³³ In other words, it is because humans ought to have dignity that they deserve to be treated equally, and with respect.²³⁴

According to Kant, human dignity stems from the human capacity for freedom and rationality, and mandates that human beings are never to be treated as mere means, but

²²⁶ *ibid* 54; Beyleveld D and Brownsword R (n 218) 70; Jowitt J, ‘Monkey See, Monkey Sue? Gewirth’s Principle of Generic Consistency and Rights for Non-Human Agents’ (2016) 19 *Trinity C.L. Rev.* 71, 88.

²²⁷ *cf.* Gewirth A, *Reason and Morality* (n 209) 53 and 62-63.

²²⁸ den Hartogh G, ‘Is Human Dignity the Ground of Human Rights?’ in Düwell M et al (eds), *The Cambridge Handbook of Human Dignity: Interdisciplinary Perspectives* (CUP 2014) 200.

²²⁹ *cf.* *ibid* 201; Bayefsky R, ‘Dignity, Honour, and Human Rights: Kant’s Perspective’ (2013) 41 *Political Theory* 809, 810 and 817.

²³⁰ Bayefsky R (n 229) 817-818.

²³¹ *ibid* 809-810 and 817-818.

²³² Basic Law for the Federal Republic of Germany (23 May 1949) [German Constitution], Article 1(1); see thereto: Bayefsky R (n 229) 810.

²³³ ICESCR (n 84) Preamble; International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) [ICCPR], Preamble; see thereto: Bayefsky R (n 229) 810.

²³⁴ den Hartogh G (n 228) 202.

as ends in themselves.²³⁵ For Kant, however, dignity is connected to morality rather than to simply being human. It therefore remains unclear whether for him dignity attaches to the moral capacity or to the actual moral conduct of a person.²³⁶ It seems, that Kant adopted a two-fold approach to dignity in that a realised dignity depends on the actual moral conduct of a human agent, while an initial dignity applies to every human being irrespective of behaviour.²³⁷ While persons who fail to act according to their dignity may therefore become subject to contempt, all human beings nevertheless deserve respect inherent to their basic dignity.²³⁸

While the contemporary view of human dignity understands the concept ‘as a source of claims toward others’,²³⁹ those claims are not further specified other than that every human being has the right that his/her dignity is respected. As the worth of human beings and their rationality ultimately depend on their capability to freely engage in action, human agency must be seen as a prerequisite for human dignity. Therefore, while it is not within the scope of this analysis to provide a conclusive enumeration of all the rights entailed within human dignity, it is suggested that at least the Gewirthian basic needs for human agency – i.e. freedom and basic well-being – also constitute the basic needs for human dignity; to which, according to the Principle of Generic Consistency (PGC), as elaborated below in 3.2.2.3, every human being is entitled. For human dignity, however, it is submitted that the aforementioned basic needs only constitute the absolute minimum requirements, and that the listed goods therefore are non-exhaustive. As human dignity entails the equal and respectful treatment of every human being, it can be submitted that the realisation of human dignity requires more than the mere realisation of freedom and basic well-being.

3.2.1.3 Ethics: Moral Philosophy and the Identification of a Supreme Moral Principle

After elaborating on the concept of morality and the essential human interests that ground moral obligations, the following analysis explores the concept of ethical studies

²³⁵ Bayefsky R (n 229) 811; Giesinger J, ‘Kant on Dignity and Education’ (2012) 62 Educational Theory 609, 609.

²³⁶ Bayefsky R (n 229) 815.

²³⁷ Giesinger J (n 235) 612.

²³⁸ *ibid* 613.

²³⁹ *ibid* 610.

to indicate how morality can be applied to identify 'goodness', and whether it is possible to identify a generally valid supreme moral principle.

Ethics, in essence, is the philosophical study of morality, or moral philosophy.²⁴⁰ One of the basic questions of moral philosophy, on a normative ethical level, is whether and if so how, it is possible to identify a framework of moral norms that is valid for everyone, providing an accurate and justified definition of moral rightness.²⁴¹ Moral philosophy thus tries to identify principles according to which anyone, in any situation can assess how he/she ought to act.²⁴² For this, a rational foundation, i.e. the correctness of purposes and principles on which moral obligations can be based, needs to be established.²⁴³ In reality, the identification of an indisputable principle of moral correctness is contentious, as can be seen from the wide variety of diverging moral philosophies that have emerged throughout human history. Adopting an egalitarian and non-universalist view, ethical relativists, for example, contend that different persons and groups have different understandings of what constitutes well-being and moral goodness.²⁴⁴ Thus, moral values are regarded as being dependent on societal and cultural contexts.²⁴⁵ Ethical relativism therefore rejects the existence of a unitary universal moral principle applicable to all human beings, and rather regards morality as relative to the epoch, the location, and the culture of where it is found.²⁴⁶ Nevertheless, it can be suggested that a great number of moral systems share common denominators in that they agree to a certain extent that moral conduct promotes what is good for the community. At the same time, it must be acknowledged that not all cultures at all times shared this consideration of goodness, and that some cultures actively rejected the dignity of certain peoples on discriminatory grounds, such as, for example, the Nazi regime in Germany. It can be suggested, however, that while certain cultures at certain times have rejected human dignity in some form or another, the

²⁴⁰ cf. Taylor PW, 'What Is Morality? Introduction' (n 207) 3-6.

²⁴¹ *ibid* 7 and 9-10; Gewirth A, *Reason and Morality* (n 209) 2.

²⁴² McInerney R, 'Aquinas's Moral Theory' (1987) 13 *Journal of Medical Ethics* 31, 31; Taylor PW, 'Classical Utilitarian Ethics: Introduction' in Taylor PW (ed), *Problems of Moral Philosophy: An Introduction to Ethics* (2nd edn, Dickenson Publishing Company 1972) 137.

²⁴³ Gewirth A, *Reason and Morality* (n 209) 2; Taylor PW, 'What Is Morality? Introduction' (n 207) 7-8.

²⁴⁴ Gewirth A, *Reason and Morality* (n 209) 10; Raphael DD, *Moral Philosophy* (OUP 1981) 11.

²⁴⁵ Taylor PW, 'Ethical Relativism: Introduction' in Taylor PW (ed), *Problems of Moral Philosophy: An Introduction to Ethics* (2nd edn, Dickenson Publishing Company 1972) 39.

²⁴⁶ Stace WT, 'Ethical Relativity' in Taylor PW (ed), *Problems of Moral Philosophy: An Introduction to Ethics* (2nd edn, Dickenson Publishing Company 1972) 51.

underlying ethical concepts have been retrospectively condemned as immoral, for example with the adoption of the UDHR.

But even in universalist moral theories, discrepancies arise particularly regarding the question of whose interests and which interests should be emphasised, especially when the interests of the actor differ from those of other persons.²⁴⁷ In this regard, analytical ethics – or meta-ethical studies – analyse the concepts of morality, seeking to resolve the question of what constitutes goodness in order to determine whether certain moral ends and rules can be considered as more correct than others.²⁴⁸ This cannot simply be answered by referring to a generic moral point of view, as moral opinions vary widely among different moral philosophies.²⁴⁹ While the naturalistic position sees goodness in actions that promote human happiness – or human well-being as the most basic form of happiness – discrepancies remain when considering whose happiness should be prioritised in cases of conflict.²⁵⁰ According to utilitarianism, for example, morally right conduct is regarded objectively and seen in actions that result in the greatest increase of happiness, with the lowest increase of unhappiness, for the greatest number of persons.²⁵¹ Utilitarianism is thus concerned with the happiness of society at large.²⁵² The theory is frequently criticised, however, for its neglect of individual rights – particularly where an overall increase in happiness severely impacts on the lives of individuals whose interests are neglected – as actions pursuing the greatest amount of happiness for the greatest number of persons may inevitably also produce unhappiness for other groups of persons.²⁵³ Furthermore, it is questionable how the greatest amount of happiness and the lowest amount of unhappiness can be measured objectively, considering that happiness is perceived subjectively differently by individuals.

In what he calls *the problem of the independent variable*, Gewirth therefore questions ‘whether there are any objective independent variables that serve to determine the

²⁴⁷ Gewirth A, *Reason and Morality* (n 209) 2.

²⁴⁸ *ibid* 2-3; Taylor PW, ‘What Is Morality? Introduction’ (n 207) 9-10.

²⁴⁹ Gewirth A, *Reason and Morality* (n 209) 4.

²⁵⁰ *ibid* 4-5.

²⁵¹ Little IMD, *Ethics, Economics, and Politics: Principles of Public Policy* (OUP 2002) 39; Raphael DD (n 244) 39; Sidgwick H, ‘Utilitarianism’ (2000) 12 *Utilitas* 253, 253 and 255; Taylor PW, ‘Classical Utilitarian Ethics: Introduction’ (n 242) 139.

²⁵² Sidgwick H (n 251) 253-255.

²⁵³ *ibid* 256; Little IMD (n 251) 53.

For further details on the distribution of happiness and unhappiness among different groups, see: Taylor PW, ‘Classical Utilitarian Ethics: Introduction’ (n 242) 147-149.

correctness or rightness of moral judgements.²⁵⁴ In view of the variety of answers provided to ethical questions by the different moral philosophical concepts, Gewirth contemplates whether it is possible to rationally advocate the existence of a supreme moral principle, which provides a unitary and universally valid interpretation of morally right conduct.²⁵⁵ As a supreme moral principle thus needs to be capable of resolving all moral conflicts, it is necessary to establish a single precept encompassing all justified moral positions.²⁵⁶ This idea, however, has been criticised on the basis that different valid moral values may stand in contrast with each other, and that therefore a supreme moral principle itself may be in conflict with another justified moral value.²⁵⁷ Then again, a supreme moral principle constitutes the very foundational moral concept from which all other moral rules derive their justification, while the supreme principle itself is not dependent on any other justification.²⁵⁸ This assumption, however, raises the conundrum of how a supreme moral principle can have validity, as it must in itself be justified; because if it was dependent on any other justification, this other justification would in fact need to be superior to the supreme principle, which thereby could not logically be supreme in the first place.²⁵⁹ The existence and logical derivation of a supreme moral principle is elaborated in the next section, by analysis of Kant's 'Categorical Imperative', and Gewirth's 'Principle of Generic Consistency' (PGC).

3.2.2 The Supreme Moral Principle

As elaborated above, a supreme moral principle is an objective universally valid norm, prescribing what is morally correct. Both Kant and Gewirth considered the concept of such a supreme moral principle in their extensive philosophical scholarship, aiming to logically derive its existence and validity. In this respect, Kant sees the supreme moral principle in the 'Categorical Imperative' which is based on the concepts of rationality and universality, while Gewirth sees the supreme moral principle in the 'Principle of Generic Consistency' (PGC) which is based on the concept of human action, and the

²⁵⁴ Gewirth A, *Reason and Morality* (n 209) 5.

²⁵⁵ *ibid* 7.

²⁵⁶ *ibid* 14.

²⁵⁷ *ibid*.

²⁵⁸ *ibid* 15.

²⁵⁹ *cf. ibid*.

agency required to engage in action. The following section of this chapter elaborates on Kant's and Gewirth's philosophical theories to indicate the existence of a supreme moral principle, and to scrutinise its applicability to the concept of human dignity. In essence, a brief introduction to Kant's conceptualisation of the Categorical Imperative is intended to simply illustrate how a supreme moral principle can be deduced, based on considerations of universality and humanity. The analysis then turns its focus on Gewirth, who, while not strictly following the Categorical Imperative, implicitly accounts for universality and humanity in his rational derivation of the PGC, which is based on the universality of human agency. In the context of this thesis, the supreme moral principle shall not be seen as a single rule capable of solving all moral conflicts, but rather as an underlying basic principle that guides all other rules by providing a minimum requirement for moral conduct. This basic principle could then be utilised to identify a moral hierarchy between conflicting legal norms, where international law fails to appropriately define this relation.

3.2.2.1 Kantianism and the Categorical Imperative

Kantianism is a deontological philosophy that prioritises the rules of moral conduct over the consequences of specific actions.²⁶⁰ For Kant, moral worth is thus not derived from the effect of an act, nor from an action that is required to achieve a desired outcome, but can only be derived from the duty to abide by the law given by a rational being.²⁶¹ In Kantianism, all moral rules are then derived from a single supreme principle of morality that Kant establishes in the 'Categorical Imperative'.²⁶² To provide guidance on how rational and universal moral rules can be identified, Kant establishes a number of formulations for the Categorical Imperative, the first two of which – namely (1) the Formula of Universality, and (2) the Formula of Humanity –

²⁶⁰ Taylor PW, 'Deontological Ethics and Criticisms of Utilitarianism: Introduction' in Taylor PW (ed), *Problems of Moral Philosophy: An Introduction to Ethics* (2nd edn, Dickenson Publishing Company 1972) 197.

²⁶¹ Kant I, 'Fundamental Principles of the Metaphysic of Morals' in Taylor PW (ed), *Problems of Moral Philosophy: An Introduction to Ethics* (2nd edn, Dickenson Publishing Company 1972) 219.

²⁶² Raphael DD (n 244) 55; Taylor PW, 'Deontological Ethics' (n 260) 199.

are of relevance for this analysis, to provide an understanding of how a supreme moral principle can be deduced.²⁶³

First, the Formula of Universality prescribes:

[A]ct only according to that maxim through which you can at the same time will that it become a universal law.²⁶⁴

To be accepted by every person of good will, a moral rule needs to be necessary and universal in that it is applied to everyone without exception, meaning that everyone and anyone is required to act in the same way in a given situation.²⁶⁵ According to this principle, morally right conduct is required to be impartial, meaning that it is not permissible for actors to make exceptions for themselves. Actors thus always need to consider whether they would be happy for everyone else to act in the same way as they do.²⁶⁶ Kant therefore goes on to stipulate:

[S]o act as if the maxim of your action were to become by your will a universal law of nature.²⁶⁷

Second, the 'Formula of Humanity' prescribes:

So act that you use humanity, in your own person as well as in the person of any other, always at the same time as an end, never merely as a means.²⁶⁸

An emphasis in the second formulation needs to be placed on the term 'merely'. In human interactions, we regularly and justly treat other human beings as means. Using other persons as means, for example, is an inherent requirement of the service industry. When employing a mechanic to repair a car, we use the mechanic as a means to our ends. At the same time, however, this employment also serves the ends of the mechanic in that he is financially compensated for the work conducted. The importance of the second formulation therefore is to be seen in the requirement that one never uses another human being *merely* as a means to achieve one's own ends.²⁶⁹ According to

²⁶³ cf. Beyleveld D and Brownsword R (n 218) 88; Kant I, 'Fundamental Principles of the Metaphysic of Morals' (n 261) 228-240; Raphael DD (n 244) 55; Taylor PW, 'Deontological Ethics' (n 260) 199-201.

²⁶⁴ Kant I, *Groundwork of the Metaphysics of Morals*, edited by Gregor M and Timmermann J (Revised edn, CUP 2012), para 4:421.

²⁶⁵ Raphael DD (n 244) 56; Taylor PW, 'Deontological Ethics' (n 260) 200.

²⁶⁶ Raphael DD (n 244) 56; Beyleveld D and Brownsword R (n 218) 89.

²⁶⁷ Kant I, *Groundwork of the Metaphysics of Morals* (n 264) para 4:421.

²⁶⁸ *ibid* para 4:429.

²⁶⁹ cf. Raphael DD (n 244) 56-57.

Kant, treating human beings as ends is to act rationally in recognition of their purpose as you recognise your own purpose.²⁷⁰ To put it differently, as all persons have to regard their ‘own existence as an end in itself’, by rational reason, every person has to regard ‘the existence of every other person [...] as an end in itself’ as well.²⁷¹

Kant’s Categorical Imperative lends itself to comparison with the so called ‘Golden Rule’, as found in a variety of ethical and religious contexts, which proclaims that one shall treat others in the same way as one would wish to be treated by them.²⁷² The Golden Rule and the second formulation of the Categorical Imperative are both frequently considered to be fundamental to ethics.²⁷³ It can be suggested that the requirement of the Categorical Imperative, to treat all human beings as an end in themselves, furthermore shares a distinct commonality with the concept of human dignity, which requires that all human beings are treated equally and with respect. Both concepts seem inherently connected to the equal worth of all human beings, and rationally derive their validity based on human existence as such. Thereby, the inherent value of every person is acknowledged, as all actors are required to validate the rights and interests of all other persons in the same way that they validate their own rights and interests. However, as Kant considers the Categorical Imperative to be the supreme moral principle, he derives its justification *a priori* by reason rather than by the nature of humanity or concerns of human dignity.²⁷⁴ Kant explicitly excludes benevolence and compassion for others as being the motivation for moral conduct from his principle of morality. Nevertheless, regard for others, by recognising the equal worth of all human beings, which is inherent to the concept of human dignity, seems to be a central aspect of the Categorical Imperative as well.²⁷⁵

²⁷⁰ *ibid* 57; Taylor PW, ‘Deontological Ethics’ (n 260) 200-201.

²⁷¹ Beyleveld D and Brownsword R (n 218) 96-97.

²⁷² *cf.* Beyleveld D and Brownsword R (n 218) 96; Raphael DD (n 244) 58; Internet Encyclopedia of Philosophy (IEP), ‘The Golden Rule’ <<https://www.iep.utm.edu/goldrule/>> accessed 24 May 2019.

²⁷³ Raphael DD (n 244) 59.

²⁷⁴ Giesinger J (n 235) 613; Taylor PW, ‘Deontological Ethics’ (n 260) 198.

²⁷⁵ *cf.* Bayefsky R (n 229) 811; Beyleveld D and Brownsword R (n 218) 91.

3.2.2.2 *From Kant to Gewirth*

For Kant, the moral rightness of an act is not dependent on its consequences, but only on its adherence to a valid moral rule.²⁷⁶ This is particularly problematic when multiple obligations stand in contrast to each other. In situations where two persons require help, but an actor only has the capacity to provide aid to one of them, the Categorical Imperative provides no guidance on whom help shall be provided to.²⁷⁷ Kant therefore acknowledges that the requirement to act cannot exceed an actor's capabilities, meaning that an actor is only required to do what he reasonably can perform.²⁷⁸ If it is impossible to provide help to two persons at the same time, the actor is not and cannot be morally obliged to help them both. The Categorical Imperative, however, fails to provide guidance on how to assess which person in need is more deserving of help.²⁷⁹ In such a situation, the Gewirthian concept of needs, as discussed above in 3.2.1.2, can provide appropriate parameters to assess which person requires help the most. According to Gewirth, a needs-based hierarchy can be established, which prioritises those needs that are most essential to human agency. As an illustration, and using the concept of human agency, it seems logically sensible to prioritise the needs of a person whose very basic goods of life or physical integrity are at risk, above the needs of a person whose non-subtractive goods, such as recreational property, are at risk. Gewirth then bases his concept of morality, *inter alia*, on the importance of these basic goods for human agency, and the recognition of agency as the fundamental requirement for individuals to engage in voluntary and purposeful action. Establishing action as the objective universal feature held by all persons, as elaborated in the next section, Gewirth derives his supreme moral principle from the concepts of action, and the agency required to engage in action, in what he calls the Principle of Generic Consistency.

²⁷⁶ Taylor PW, 'Deontological Ethics' (n 260) 197.

²⁷⁷ Raphael DD (n 244) 60.

²⁷⁸ *ibid.*

²⁷⁹ *ibid.*

3.2.2.3 Gewirth's Principle of Generic Consistency

For Gewirth, the determination of morality cannot be derived from empirical observations, but rather needs to be based on a feature that is universally held by all persons capable of morality, irrespective of individual opinions.²⁸⁰ This feature is simply to be regarded as 'action' itself, and thus also the agency which is required by all persons to freely engage in any action.²⁸¹ The main aim of Gewirth's concept of morality is to establish the existence of an objective supreme principle of morality, which is categorically obligatory in that it has to be logically accepted by every agent based on the simple fact that he engages in action.²⁸² Human action generally composes of two generic features, namely a) voluntariness, i.e. the freedom to engage in an action, and b) purposiveness, i.e. the intention or reasons for an actor to engage in such action.²⁸³ The agency required for action can therefore be employed as a universal criterion for morality, as everyone has to accept its validity.²⁸⁴ This is because the denial of its relevance would itself require an agent to engage in a voluntary and purposeful action.²⁸⁵ As elaborated below, by denying the supreme moral principle, an agent would thus necessarily contradict himself.²⁸⁶

Based on the universality of action, and the required agency to engage in any action, Gewirth derives his supreme moral principle from a logical progression of statements in three stages:²⁸⁷

1. When an agent engages in an action, he/she has a purpose which he/she implicitly considers to be good. Thereby, the agent considers his/her basic goods required for agency, and thereby for action – namely freedom and well-being, as elaborated above in 3.2.1.2 – as good in that they are necessary to enable him/her to act towards his/her purposes.²⁸⁸

²⁸⁰ Gewirth A, *Reason and Morality* (n 209) 5-7; Jowitt J (n 226) 80.

²⁸¹ Jowitt J (n 226) 80-81.

²⁸² Gewirth A, *Reason and Morality* (n 209) 48; Jowitt J (n 226) 80.

²⁸³ Gewirth A, *Reason and Morality* (n 209) 27.

²⁸⁴ Jowitt J (n 226) 80-81.

²⁸⁵ *ibid* 81.

²⁸⁶ Gewirth A, *Reason and Morality* (n 209) 48.

²⁸⁷ *ibid*; Jowitt J (n 226) 81.

²⁸⁸ Gewirth A, *Reason and Morality* (n 209) 48.

2. As every agent has to accept the necessity of the basic goods for acting towards the purpose he/she considers good, ‘every agent implicitly makes a deontic judgement in which he claims that he has rights to freedom and well-being.’²⁸⁹
3. It necessarily follows, that every agent has to claim these rights simply because he/she has purposes which he/she intends to fulfil. In acknowledgement of the principle of generalisation, logic then demands that every agent also has to accept ‘that all prospective purposive agents have rights to freedom and well-being.’²⁹⁰

To emphasise the importance of these statements, this derivation requires further elaboration. Notably, an agent’s evaluation of the goodness of his/her actions and purposes is subjective, and therefore does not implicitly establish the objective goodness of his/her actions.²⁹¹ The necessary means for action – namely the basic goods of freedom and well-being – however, are universally required by any agent in order for him to engage in action. Thus, Gewirth also refers to these features as ‘generic goods’.²⁹² Notwithstanding the recognition that between different groups and persons diverging views exist as to what individuals consider to be good and what is perceived to be entailed by well-being, Gewirth can demonstrate that these variations do not affect his conception of the basic goods.²⁹³

For the assertion that agents necessarily regard these contents as good is made within the context of purposive action; it indicates the preconditions necessary to the existence of any agent’s purposive actions viewed generically and collectively. Hence, since the agent regards his purposes as good, he must, insofar as he is rational, regard these conditions as at least instrumentally good, whatever his particular contingent and variable purposes and evaluations.²⁹⁴

It is due to the universal necessity of the generic goods, which all agents must hold as the generic features of their successful action, that all agents must logically claim these as rights simply because of their agency.²⁹⁵ In other words, every agent must at least claim that other agents shall not interfere with the generic goods necessary for his/her agency, which Gewirth therefore also calls ‘generic rights’.²⁹⁶ These rights are generic

²⁸⁹ *ibid.*

²⁹⁰ *ibid.*

²⁹¹ Jowitt J (n 226) 82.

²⁹² Gewirth A, *Reason and Morality* (n 209) 52.

²⁹³ *ibid* 54.

²⁹⁴ *ibid.*

²⁹⁵ *ibid* 63 and 66; Jowitt J (n 226) 82.

²⁹⁶ Gewirth A, *Reason and Morality* (n 209) 63-64 and 66.

in that they summarise all rights that are merely specifications of the rights to freedom and well-being. According to Gewirth, they are further to be regarded as superior to other rights that contradict these generic rights, and may therefore also be defined as fundamental.²⁹⁷ As the rights to freedom and well-being are the ‘most general and proximate necessary conditions of all [...] purpose-fulfilling actions,’²⁹⁸ without which any purposive action is impossible, they are human rights required by all human beings in order to occupy agency.²⁹⁹ From this fundamental necessity, Gewirth derives that the basic rights, and only these, are inviolable, so that an agent has the right to claim that all other persons not only *shall*, but *must* refrain from interfering with his generic rights.³⁰⁰

The rights as they are presented so far are claimed by individual agents in consideration of their self-interest, and are thus prudential but not moral in nature.³⁰¹ Morality is only regarded in conduct that favourably considers persons other than the actor.³⁰² According to Gewirth, however, every prospective agent can and must claim the generic rights necessary for his/her agency, so that this rights claim is made by all agents alike.³⁰³ It follows that there is a general claim to the generic rights, whereby every agent must logically accept that all agents possess the same basic rights.³⁰⁴ If an agent failed to acknowledge the generic rights of other agents, he would contradict himself in that he would be ‘both affirming and denying that being a prospective purposive agent is a sufficient condition of having rights to freedom and well-being.’³⁰⁵ In other words, every agent necessarily must admit that the grounds upon which his/her own rights are based also provide the foundation for all other agents having the same rights.³⁰⁶ The progression of this argument can thus be illustrated in simplified terms with the statement:

²⁹⁷ *ibid* 64.

²⁹⁸ *ibid* 65.

²⁹⁹ *ibid* 64-65.

³⁰⁰ *ibid* 81-82.

³⁰¹ For further reading on this, see: *ibid* 68-75.

³⁰² *ibid* 71 and 129; Jowitt J (n 226) 83.

³⁰³ cf. Gewirth A, *Reason and Morality* (n 209) 72-73.

³⁰⁴ *ibid* 74-75 and 102.

³⁰⁵ *ibid* 133; see also: *ibid* 74-75.

³⁰⁶ *ibid* 103 and 146.

*An agent has generic rights for the very reason that he is an agent. Because of their agency, all agents thus must logically possess these generic rights.*³⁰⁷

As elaborated so far, generic rights entail a negative feature that requires all agents to refrain from interfering with the basic rights of other agents. For Gewirth, generic rights are furthermore positive in that they require that agents ought to help other persons to achieve and safeguard their freedom and well-being.³⁰⁸ In other words, where persons lack the capacity to satisfy their basic needs themselves, other agents shall provide aid to the persons in need, if this can be undertaken at reasonable expense.³⁰⁹ It thus follows that the universal necessity of basic needs for human agency entails both generic rights as well as generic obligations.³¹⁰ In the light of this, derived from the above mentioned three statements and the principle of generalisation, Gewirth formulates his supreme principle of morality, called the Principle of Generic Consistency (PGC), which states:

Act in accord with the generic rights of your recipients as well as of yourself.³¹¹

The PGC derives its justification as a moral principle from two main factors: firstly, from its universality, as it is logically derived from the fact that all agents have to engage in purposive action, and, secondly, because the PGC prescribes respect for the recipients of such actions. This entails both respecting the recipients' purposive actions as well as their rights as persons in general.³¹² As a result, the PGC is a moral principle in that it is both self-regarding and other-regarding, as it requires agents to favourably consider the interests of others as well as of themselves.³¹³ The PGC thus is egalitarian in that it requires that the rights of everyone are considered equally, by prescribing that agents shall always be treated as persons.³¹⁴ In this regard, the PGC has a distinct commonality with Kant's Categorical Imperative as both principles require that human beings are not to be treated as mere means but as ends in themselves.

³⁰⁷ Beyleveld D and Brownsword R (n 218) 74; Jowitt J (n 226) 84.

³⁰⁸ Gewirth A, *Reason and Morality* (n 209) 67.

³⁰⁹ *ibid* 134-135.

³¹⁰ *ibid*.

³¹¹ *ibid* 135.

³¹² *ibid* 137-138.

³¹³ *ibid* 137; Beyleveld D and Brownsword R (n 218) 72.

³¹⁴ Gewirth A, *Reason and Morality* (n 209) 140.

For Gewirth, the PGC as the supreme moral principle is superior to all other rules of morality and/or personal interaction.³¹⁵ Rules that stand in contradiction to the PGC are thus considered to be invalid.³¹⁶ With the PGC, Gewirth provides rationally deduced answers to two of the essential questions of moral philosophy, as described above in 3.2.1.3, namely: whose interests, and which interests shall be favourably considered by morally right conduct. The PGC prescribes that the rights of all agents have to be treated equally, meaning that the generic rights held by all human agents have to be respected.³¹⁷ Furthermore, the PGC acknowledges the superiority of the generic or basic rights, i.e. it favourably considers the rights to freedom and well-being due to their essential importance for purposive action.³¹⁸ Gewirth, however, recognises further hierarchical structures within the scope of generic rights, by placing a higher emphasis on those rights that are more essential for the preservation of life itself.³¹⁹ In regard to the conceptualisation of action, this hierarchy is justified when considering that while the basic goods are required for actions to be successful, certain basic goods are essential for an agent being able to act in the first place.³²⁰ The latter is especially true for life itself and the means required to sustain life.

It must be noted that because Gewirth intends to prescribe a universally applicable supreme moral principle, his views are not unanimously accepted, and the diverging opinions are accompanied by criticism of the PGC. The PGC has been particularly criticised for being too simple, in that it derives a very strong conclusion, namely a supreme moral principle, from a rather simple premise, only basing the PGC on the concept of human agency.³²¹ A further point of criticism is that constructing a normative concept of morality, i.e. a morality that is rational in itself and independent of individual opinions, may be impossible in a pluralistic world.³²² It is submitted, however, that by eliminating subjective factors, focussing only on the objective and universal requirements for action and agency, Gewirth manages to establish the PGC

³¹⁵ *ibid* 145.

³¹⁶ *ibid*.

³¹⁷ *ibid* 150.

³¹⁸ *ibid*.

³¹⁹ *ibid* 62-63 and 150.

³²⁰ Beyleveld D and Brownsword R (n 218) 70.

³²¹ *ibid* 77.

³²² Jowitt J (n 226) 85.

as a valid moral principle, which is justified by ‘the recognition that *action* is the universal and necessary context of all moralities’.³²³

Ultimately, the PGC prescribes that all human agents are to be treated equally, and with respect to their generic rights. While the PGC may thus constitute the foundation of morally right conduct, the determination of whether Gewirth actually established the PGC as the one and only supreme moral principle exceeds the scope of this thesis, as this question requires a deeper analysis within the field of moral philosophical scholarship. For the purpose of this thesis, however, it is acknowledged that the PGC is derived by logical progressions and thereby sufficiently justified by Gewirth as an eligible moral principle. The validity of the PGC is therefore accepted here, so that the PGC is considered as a suitable principle for the determination of a moral hierarchy between international IP law and the human rights to health and life.

3.2.3 The Application of the Principle of Generic Consistency in the Context of International Law: The Moral Superiority of the Rights to Health and Life

The first part of this chapter, analysing the relationship between international human rights law, and international trade and IP law, found that because different international treaty regimes are functionally detached from each other, a clear legal hierarchy between trade rules and human rights cannot be established. Similarly, international human rights law does not provide sufficient clarification on issues arising from intra-regime conflicts between the human right to IP and the fundamental human rights to life and health. With respect to the vital importance of the human rights to life and health for the realisation of a dignified standard of living, and in order to scrutinise the justification of the current international patent regime in the next chapter, the second part of this chapter analyses moral philosophical principles, aiming to provide guidance on whether the superiority of rights protecting fundamental human interests can be ethically established. In this regard, it is proposed that based on the concept of human dignity, it can be argued that certain human rights, especially those that protect

³²³ Gewirth A, ‘Is Cultural Pluralism Relevant to Moral Knowledge?’ (1994) 11 Social Philosophy & Policy 22, 27.

human freedom and well-being, are to be prioritised over less-essential rights, such as the right to IP.

To support this argument, the first part of this analysis provided an evaluation of the scope of the concept of morality, to establish whether there is a general understanding of what is considered to constitute moral goodness. To this end, sub-chapter 3.2.1.3 indicated that moral goodness, or morally right conduct, is commonly equated with the promotion of human happiness, which in turn can be considered to entail human well-being,³²⁴ as well-being constitutes a main prerequisite for the pursuit of happiness, or, in other words, the most basic form of happiness. As morality also requires an act being other-regarding and not simply performed in the actor's self-interests, moral conduct exists in those acts that advance the well-being of other persons. Differences between the various streams of moral philosophy can be identified in the way they approach how morality should be achieved. A notable difference can be identified when comparing utilitarianism with Gewirthian ethics. For the utilitarian, moral conduct is that which brings about the greatest surplus of happiness, for the greatest number of persons. However, recognising that different types of happiness cannot be horizontally compared with each other, as the parameters that actually generate happiness for individual persons are subjective, it seems more logical to follow the Gewirthian concept of needs, prioritising those human needs that are most essential for human well-being. This concept, moreover is in accordance with the concept of human dignity which stipulates that there is a certain core value attached to humanity which must not be denied.

This analysis then explored the existence and applicability of a supreme principle of morality – i.e. a moral principle that supports the prioritisation of certain rights above any other considerations – by scrutinising the Kantian 'Categorical Imperative' and the Gewirthian 'Principle of Generic Consistency'. Both principles share distinct commonalities in that they both acknowledge the inherent value of all human beings by stipulating that all persons must be regarded as ends in themselves. They are further closely related to the Golden Rule, as all three principles emphasise that other persons ought to be treated in the same way as one wishes to be treated by them. As this rational consideration of the equal worth of all persons lies at the heart of morality, the

³²⁴ Little IMD (n 251) 39.

Categorical Imperative and the PGC can both be regarded as providing fundamental moral principles. A supreme moral principle, however, needs to be justified in itself. While the differences between the content of the Categorical Imperative and the PGC are marginal, the main distinction between the two principles is the way in which their applicability is derived. For Kant, the applicability of the Categorical Imperative stems from duty, i.e. the duty to abide by valid moral rules. This, however, leaves the question of where that duty comes from. Further, by only stipulating that human beings shall never be treated as mere means, Kant does not establish measures to evaluate what type of interests are to be prioritised in situations of conflict, which can arise even where all parties concerned are treated as ends in themselves. Gewirth, in comparison, bases the PGC on agency and the universally necessary requirements for purposive action. In doing so he manages to determine that rational logic demands agents to accept that all agents have the same rights simply based on the virtue of their agency. While it may be submitted that due to the close similarity between the Categorical Imperative and the PGC, the Categorical Imperative could also be based on human agency, by actually employing human agency as the determining factor, Gewirth can establish that there exists a hierarchy of rights prioritising the most essential needs for agency over second-order needs. Consequently, the greatest emphasis is placed on life itself, granting superiority to all goods that are necessary to sustain life.³²⁵ The PGC is therefore not only in itself justified as the supreme moral principle, but further establishes which interests ought to be prioritised in situations of conflict.

Acknowledging that the basic or generic needs of human agency likewise constitute the most basic preconditions for a human life in dignity, the PGC can be employed to evidence the superior importance of protecting human dignity. Consequently, by considering that denying the PGC is to contradict one's very own agency, it can also be suggested that denying the PGC is to contradict one's own human dignity.³²⁶ The PGC therefore provides a rational moral justification for the fundamental concept of human dignity. This connection to human dignity is of particular importance for this thesis, because human rights are derived from the dignity inherent to all human beings, as elaborated above in 3.1.1. As a result, it is proposed that the PGC can be utilised as

³²⁵ Gewirth A, *Reason and Morality* (n 209) 62-63.

³²⁶ Beyleveld D and Brownsword R (n 218) 110.

a means of identifying and prioritising those human rights that are most important for human dignity over less essential rights.³²⁷

The PGC can then be employed as the basis for providing a positive answer to Research Question 2:

Are there valid moral principles that can be utilised to justify the prioritisation of the right to health over contradictory provisions of international trade law and patent law?

By providing that all human agents have equal rights to the generic needs necessary for agency, the PGC is in accordance with the basic considerations of egalitarian ethics. By deriving the PGC from the fundamental requirements for human agency and purposive action, Gewirth can further establish that the PGC is in itself justified and therefore may reasonably constitute the supreme principle of morality. By applying the needs-based conceptualisation of the PGC to the concept of human dignity, the moral principle can be utilised to address challenges of norm-conflicts in the legal domain. Considering that human dignity, as recognised by all major human rights instruments, is intrinsic to human existence, the basic rights emphasised by the PGC cannot be denied, so that it is applicable regardless of personal opinions or acceptance. Thus, for Gewirth generic rights are of such importance that they exist independently from any culture or community,³²⁸ and thereby exist independently from their legal recognition. Furthermore, the recognition that human rights shall provide protection against wrongs that no human being should experience, by providing limitations to the power of governments, indicates the existence of legally recognised values that are superior to any other considerations.³²⁹ The present analysis thus indicates that the protection of the most fundamental human needs imposes moral obligations that are binding irrespective of personal beliefs. It is the unconditional universal necessity of those fundamental needs that further elevates the requirement to adhere to such moral principles above any contradictory legal obligations. As the purpose of law may arguably be seen in the regulation of human behaviour by way of reinforcing moral obligations, the question arises of whether morally flawed laws can be regarded as

³²⁷ cf. *ibid* 86.

³²⁸ Gewirth A, *Reason and Morality* (n 209) 74.

³²⁹ cf. Little IMD (n 251) 27 and 29.

legitimate.³³⁰ It thus follows that legal norms ought to be in accordance with valid moral rules protecting fundamental human interests. Therefore, it is sensible to suggest that the PGC, and in particular the rights to freedom and well-being, should constitute the standard against which the legitimacy of all other laws is scrutinised.³³¹

3.3 Concluding Remarks

As indicated at the outset of this chapter, it is essential for the examination of the justification of the international patent regime in the next chapter, to establish the parameters against which this justification can be scrutinised. To this end, the first part of this chapter analysed the existence of a legal hierarchy under international law, which prioritises either human rights or trade/IP concerns in cases of norm conflicts, concluding that such a hierarchy currently cannot be established. For this reason, the second part of this chapter considered whether other considerations support the prioritisation of certain rights, against which the justification of the international patent regime can be examined, by analysing moral and ethical concepts. The analysis concluded that the needs-based hierarchy, established by Gewirth in his derivation of the Principle of Generic Consistency, suggests the superiority of those rights that are most essential for the realisation and protection of human life and well-being. It is therefore proposed that when the concept of basic human needs is applied to the concept of human dignity, the PGC can be utilised to morally justify the prioritisation of those human rights that protect human dignity over provisions of international trade law and patent law. Thus, for the purpose of the analysis of the justification of the international patent regime – with a particular reference to the patentability of medical products – human rights that are most essential for human dignity are considered of greater importance than TRIPS and TRIPS-Plus patent laws. Therefore, this thesis claims priority to the right to health, based on moral and ethical considerations. Consequently, in the next chapter, the justification of the international patent regime is scrutinised, *inter alia*, against its compliance with the right to health.

³³⁰ Ehrenberg KM (n 215) 82-83.

³³¹ Jowitt J (n 226) 83.

Chapter Four

4 The Justification of the International Patent Regime

4.1 Introduction

The following chapter provides an analysis of the justification of the international patent regime with respect to the patentability of medical products, and the implications of this to human health and life, with a particular focus on the accessibility of medicines in developing countries. As elaborated in the previous chapter, there are moral reasons founded on the needs-based hierarchy which suggest that it is sensible to prioritise those human rights most essential for human life in dignity over any other legal considerations. Following this concept, the present analysis scrutinises the justification of the patentability of medical products against the right to health, which includes a right to accessible and affordable medicines for everyone, as discussed in chapters 1.2.1.1 and 1.4. In cases of norm conflicts between the international patent regime and the human rights to health and life, this analysis will therefore prioritise the relevant human rights concerns over the provisions of international IP law. One of the main issues in such conflicts is the identification of the right balance. There is ample reason to reaffirm the importance of the right of authors and inventors to be compensated for investments made in the development of new inventions, and it must be acknowledged that adequate incentives to conduct further research are essential for

the advancement of medical knowledge.¹ It does not seem to be justified, however, that such compensation is provided at the cost of human health and life. As elaborated in chapters 3.1.2.2 and 3.1.3.2, human rights documents have regularly taken account of the IP interests of authors and inventors, while international IP laws have paid little regard to related human rights issues.² The current international IP regime thus neglects the emphasis on public benefits as provided for by human rights law, and instead focusses mainly on the private rights of authors and inventors, which is detrimental to the establishment of an adequate balance.³

While concerns about the accessibility, and particularly the affordability, of medicines are at the heart of this inquiry, this analysis will scrutinise all aspects of the right to health including the importance of incentivising research in order to advance pharmaceutical innovation to address health concerns in the future. As innovation, however, is insufficient for realising the right to health when the resulting medical products are unaffordable for patients in desperate need of treatment, concerns of affordability constitute the main factor against which the justification of the international patent regime needs to be scrutinised. While the issue of affordable medical products is of high importance for all countries, a particular focus on developing countries is applied because of the severe impacts increased prices on medicines have on the public health situation of countries with high levels of poverty. Furthermore, this analysis will not only take into consideration the public health concerns of developing nations, but also the implications of the international patent regime on the development process of poorer countries. To do this, this chapter elaborates the shortcomings of the current international patent regime, identifying issues that require amendment in order for the regime to be considered as justified from a moral and human rights point of view.

The following analysis addresses Research Question 3:

Recognising the importance of the right to health and access to medicines for human life in dignity, is the current international patent regime (under TRIPS

¹ cf. Hestermeyer H, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (OUP 2007) 137.

² Cullet P, 'Patents and Medicines: The Relationship between TRIPS and the Human Right to Health' (2003) 79 *International Affairs* 139, 140 and 144.

³ *ibid* 152.

and TRIPS-Plus) justified when the protection of private interests directly impacts on the affordability of medicines and public health?

The answer to this question is reached by scrutinising the two Sub-Questions:

3.1: Do the aims and purposes of patents justify a short-term restriction of the accessibility of medicines?

3.2: Do patents on pharmaceutical products actually fulfil their purposes and objectives?

The results of these sub-questions will then be analysed to answer Research Question 3. To this end, sub-chapter 4.2, addressing the first sub-question, compares the pro patent arguments and the purposes of the international patent regime with the immediate negative impacts of the patentability of pharmaceutical products. The analysis then considers the balance between human rights and patent rights, before concluding that there is a controversy regarding the justification of short-term restrictions of the accessibility of patented medicines for the purpose of advancing medical research. It is then concluded that in order to be justified, the international patent regime is required to adequately fulfil its objectives and purposes. In this regard, sub-chapter 4.3 provides an argument establishing that patents do not fulfil their purposes, by particularly scrutinising how far patents actually provide an adequate incentive to conduct meaningful research into truly novel pharmaceutical products, and how far the international IP system actually fulfils its purposes of facilitating technology transfer to developing countries, and increasing foreign direct investment (FDI) in those countries. Lastly, sub-chapter 4.4 then proposes an answer to the main Research Question 3, which can be derived from the answers to the two Sub-Questions 3.1 and 3.2, providing an argument that due to the non-fulfilment of its purposes and objectives, the current international patent regime is not justified. It is therefore proposed that amendments to the system are required in order to adequately harmonise the rights and obligations of patent holders, thereby establishing a balance between human rights demands and patent rights.

4.2 Do the Aims and Purposes of Patents Justify a Short-Term Restriction of the Accessibility of Medicines?

4.2.1 Arguments Pro Patents

The main positive aspect supporting the public interest generated by patent rights originates from the requirement that patents are granted in exchange for the disclosure of knowledge about the technicalities of an invention. Thereby, patents provide a trade-off that ensures that inventions are not kept as trade secrets by the originator, and thus can be freely used for the public benefit once a patent period expires, leading to an enhanced availability of useful products.⁴ It can therefore be deduced that patents themselves provide the foundation for cheaper generic competition as the disclosure requirement enables generic manufacturers to enter the market once a patent expires, without facing high research costs.⁵ Thus, it can be suggested that the exception to free-trade and anti-monopoly regulations provided by patent rights is balanced, to a certain degree, by the required disclosure of the invention and the timely limitation of the exclusive rights.⁶

Furthermore, a main reason for patents being offered to inventors is the creation of an incentive to be innovative.⁷ The premise of stronger patent protection therefore is to increase encouragement for the development of new products.⁸ It is generally accepted that, particularly in the field of pharmaceuticals, the research and development (R&D) of new products involves substantially high costs, ranging from between \$115m and \$802m for the development of a single new drug.⁹ Additionally, pharmaceutical

⁴ cf. Dutfield G, 'Healthcare Innovation and Patent Law's "Pharmaceutical Privilege": Is there a Pharmaceutical Privilege? And if so, should we remove it?' (2017) 12 HEPL 453, 453; United Nations Economic and Social Council (ECOSOC), 'The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights' (27 June 2001) Un Doc E/CN.4/Sub.2/2001/13, para 11.

⁵ cf. Phillips AA, 'Strengthen Pharmaceutical Patent Rights: Lowering the Cost of Prescription Drugs by Stopping the Reckless Patent Litigation Abuse of Generic Companies' (2006) Conn. Ins. L. J. 397, 407.

⁶ Cullet P (n 2) 140; Lucyk S, 'Patents, Politics and Public Health: Access to Essential Medicines Under the TRIPS Agreement' (2007) 38 Ottawa Law Review 191, 207.

⁷ cf. ECOSOC (n 4) para 11.

⁸ Abbott FM, 'Trade in Medicines' in Smith R and others (eds), *Trade and Health: Towards Building a National Strategy* (WHO 2015) 135.

⁹ *ibid* 128; ECOSOC (n 4) para 37; Hestermeyer H (n 1) 142 and 159; Lucyk S (n 6) 206. Phillips even suggests that the development costs of new pharmaceutical products averages at \$897m. See: Phillips AA (n 5) 406.

research is a high-risk investment, as new drugs are required to go through expensive and risky clinical trials before being approved for marketing, so that shareholders commonly demand high returns in order to be willing to make such investments.¹⁰ A particular problem in the field of pharmaceuticals is that due to the lengthy research efforts and clinical trials required for marketing approval, the effective exclusive market protection of patents is shorter for medical products than for innovations in other fields of technology, and lasts, on average, for 11 years only.¹¹ Furthermore, as a large proportion of pharmaceutical R&D is unsuccessful, with only one in five drugs in clinical testing being ultimately approved for marketing, novel medications that do succeed need to be capable of not only recouping their own R&D costs, but also compensating a corporation's expenses into the R&D of unsuccessful products.¹² Thus, if patents were too restrictive to provide adequate returns on pharmaceutical research, there would be the likelihood of investments being shifted to more profitable fields of technology.¹³

For these reasons, the research-based industry relies on patent protection to attract investors willing to support the development of new medical products. Patents, by providing exclusive rights to inventors, facilitate the successful commercialisation of new medical products, and therefore create the required research incentive by promising investors a period of monopoly position on the market which can be used to recover R&D costs and to make higher profits.¹⁴ In the end, it must be acknowledged that the investment into pharmaceutical research today is expected to have substantial benefits for future health.¹⁵ In consideration of the right to health, it must be remembered that not only the affordability of current medications is of concern, but

¹⁰ Abbott FM, 'Trade in Medicines' (n 8) 128; Michelsohn A, 'Drug-Patent Abuse and the High Cost of Healthcare: Case of the Double-Half Dose-Time Injection' (*IP Watchdog*, 20 March 2018) <<https://www.ipwatchdog.com/2018/03/20/drug-patent-abuse-high-cost-healthcare/id=95056/>> accessed 23 April 2018; Reichman JH, 'Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) *Pharmaceutical Regulations* 247, 257.

¹¹ Phillips AA (n 5) 406.

¹² *ibid*; Lucyk S (n 6) 206-207.

¹³ Abbott FM, 'Trade in Medicines' (n 8) 128.

¹⁴ Abbott FM, 'Intellectual Property and Public Health: Meeting the Challenge of Sustainability' (2011) *Global Health Programme Working Paper No7/2011*, 9 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1965458> accessed 22 May 2019; Flynn S, Hollis A and Palmedo M, 'An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries' (2009) 37 *Journal of Law, Medicine & Ethics* 184, 186; ECOSOC (n 4) para 11.

¹⁵ Henry D and Searles A, 'Chapter 9: Pharmaceutical Pricing Policy' in *Management Sciences for Health, MDS-3: Managing Access to Medicines and Health Technologies* (3rd edn, Management Sciences for Health 2012) 9.2 and 9.7.

that innovation is essential in the field of pharmaceuticals to advance the treatment of diseases for the future.¹⁶ Therefore, by providing a research incentive for the development of new cures to address disease burdens, patents not only serve the interests of the industry, but can further serve an undeniably positive purpose for public health.¹⁷

In comparison to other fields of technology, the pharmaceutical industry seems to be especially dependent on patent protection due to the high costs involved in medical R&D and clinical trials, and the comparatively low costs required for the manufacturing of generic copies.¹⁸ Information, like the knowledge of the technicalities of an invention, generally can be regarded as a public good, which once it becomes available can be used by anyone without any benefit for the creator.¹⁹ Thus, after the initial development of new pharmaceutical products, it is comparatively simple for a competitor to copy the drugs.²⁰ Generic manufacturers can thus offer lower prices as they are not required to recover high investments made into R&D and clinical trials.²¹ For this reason, a perfectly competitive market does not provide adequate incentives for expensive high-risk research undertakings, as market prices determined by copied competition lowers prices to a level close to the production costs without taking account of the other costs involved in the R&D process.²² Therefore, there exists a market failure in that the free market is not capable of adequately facilitating inventiveness.²³ Without patents, originator companies would be at risk of losing their investments as competitors could simply make profits by free-riding on an inventor's expenses, with the added advantage of being able to provide cheaper prices.²⁴ Without patent protection, the substantial costs and risks of pharmaceutical research could discourage innovation due to the real prospect of impaired profitability.²⁵ Arguably, without patent protection a large number of available

¹⁶ Abbott FM, 'Trade in Medicines' (n 8) 117.

¹⁷ *ibid* 120; Phillips AA (n 5) 407.

¹⁸ Cullet P (n 2) 141; Dutfield G, 'Healthcare Innovation and Patent Law's' (n 4) 462; ECOSOC (n 4) para 37.

¹⁹ Lucyk S (n 6) 206; Smith RD, Correa C and Oh C, 'Trade, TRIPS, and Pharmaceuticals' (2009) 373 *The Lancet* 684, 685.

²⁰ Phillips AA (n 5) 413.

²¹ Henry D and Searles A (n 15) 9.8.

²² Hestermeyer H (n 1) 141-142.

²³ *ibid* 141; Lucyk S (n 6) 206.

²⁴ Hestermeyer H (n 1) 142; Phillips AA (n 5) 406.

²⁵ Phillips AA (n 5) 412.

medications may never have been invented.²⁶ Given these points, it can be suggested that patents safeguard the future development of new medicines by rewarding innovators and protecting inventors against unauthorised use of their inventions.²⁷ It is further claimed by the industry that the patentability of new uses of known substances – as included in a number of TRIPS-Plus FTAs – provides incentives for conducting continued research into already patented drugs to find potential additional benefits.²⁸ This is a controversial issue, however, as the availability of second use patents also facilitates strategic planning to prolong exclusive rights without providing any substantial added benefits; a strategy which is known as patent ‘evergreening’, as explained in chapter 2.5.1.1, and further elaborated below in 4.3.2.3.

Additionally, it is claimed that a generally heightened level of IP protection in developing countries is beneficial in that it arguably leads to the development of domestic R&D capacity, and that the overall strengthening of the international patent system would lead to higher levels of innovation globally, for the benefit of all countries.²⁹ This can be exemplified by considering that in the wake of the TRIPS Agreement, Indian pharmaceutical companies, which traditionally focused their activity on the production of generic drugs, began to increase investments into their own R&D capacity, seeking to develop new innovative medicines themselves.³⁰ Furthermore, heightened IP standards arguably make developing countries more attractive for FDI implying an overall benefit for those countries.³¹ This argument is derived from the consideration that investors in knowledge based industries may be reluctant to make investments in countries with insufficient IP standards due to an insufficient protection against piracy.³²

The patentability of pharmaceuticals in developing countries is further defended by the research-based industry as a necessary requirement for keeping patented drugs at profitable prices in industrialised nations in order to recoup research investments. This

²⁶ *ibid* 405; Hestermeyer H (n 1) 158; Lucyk S (n 6) 206.

²⁷ Cullet P (n 2) 140; Hestermeyer H (n 1) 158; Smith RD, Correa C and Oh C (n 19) 685.

²⁸ *cf.* Phillips AA (n 5) 407.

²⁹ Turk M, ‘Bargaining and Intellectual Property Treaties: The Case for a Pro-Development Interpretation of TRIPS but not TRIPS Plus’ (2010) 42 *International Law and Politics* 981, 1000-1001.

³⁰ Phillips AA (n 5) 412.

³¹ *cf.* Turk M (n 29) 1001.

³² Richards DG, ‘A Skeptik’s View of Intellectual Property Rights’ in Bird RC and Jain SC (eds), *The Global Challenge of Intellectual Property Rights* (Edward Elgar Publishing 2008) 272.

argument is connected to the fear of the industry that cheaper prices may leak into developed markets as consumers may challenge high prices when cheaper drugs are available in developing countries.³³ This suggestion, however, seems to be redundant as consumers in developed markets are aware of the poverty in developing countries and for decades have accepted that wealthy countries indirectly subsidise cheaper medications in developing countries.³⁴

4.2.1.1 Objectives and Purposes of the International IP Regime

When scrutinising the arguments in support of patent rights, it is of essential importance to take into consideration the general objectives and purposes of the international IP system. As established so far, the main purpose of patents is to foster innovation and to facilitate technological development.³⁵ Additionally, for patents under the WTO regime, a wider perspective needs to be adopted, taking account of the objectives of the WTO which include the clear goal of ‘raising standards of living’.³⁶ Thus, when regarded in correlation with the statement of Art XX(b) of the GATT 1994, which provides members with the right to adopt measures ‘necessary to protect human, animal or plant life and health’, and Art 8(1) TRIPS which facilitates the adoption of measures ‘necessary to protect public health and nutrition’, it can be suggested that an integral purpose of the international patent regime is the protection and promotion of public health.³⁷ Furthermore, the objectives of TRIPS emphasize the mutual advantage to both the producer and the user of technological knowledge, and particularly references the importance of social and economic welfare including the need for an

³³ Abbott FM, ‘WTO TRIPS Agreement and its Implications for Access to Medicines in Developing Countries’ (2002) United Kingdom Commission on Intellectual Property Rights, Study Paper 2a/2002, 7 <<https://ssrn.com/abstract=1924420>> accessed 11 October 2018; Hestermeyer H (n 1) 165.

³⁴ Abbott FM, ‘WTO TRIPS Agreement and its Implications’ (n 33) 7.

³⁵ cf. Cullet P (n 2) 140.

³⁶ Marrakesh Agreement Establishing the World Trade Organization (signed 15 April 1994, entered into force 1 January 1995) [WTO Agreement], Preamble; Guan W, ‘IPRs, Public Health, and International Trade: An International Law Perspective on the TRIPS Amendment’ (2016) 29 *Leiden Journal of International Law* 411, 414.

³⁷ General Agreement on Tariffs and Trade 1994, Annex 1A of the Marrakesh Agreement Establishing the World Trade Organization (signed 15 April 1994, entered into force 1 January 1995) [GATT 1994], Article XX(b); Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (signed 15 April 1994, entered into force 1 January 1995) [TRIPS Agreement], Article 8(1); See thereto: Guan W (n 36) 414; Frankel S, ‘Challenging TRIPS-Plus Agreements: The Potential Utility of Non-Violation Disputes’ (2009) 12 *JIEL* 1023, 1037-1038.

adequate balance between rights and obligations of IP rights holders.³⁸ The TRIPS Agreement, however, does not provide further details on how such a balance shall be achieved.³⁹

4.2.2 Immediate Negative Impacts of Pharmaceutical Patentability

While providing a valuable incentive for innovation, patents also come at a cost for society.⁴⁰ Particularly in the field of pharmaceuticals this is a great social cost to bear. Patents are likely to aggravate the problem of access to medicines in developing countries, as the existence of competition has considerable impact on the price and availability of pharmaceuticals.⁴¹ In a perfectly competitive market, competition reduces prices because potential customers have the freedom to choose from different offers.⁴² Here, sellers only receive regular revenues which cover productions costs and a slight profit.⁴³ Any increased revenue margins would attract further competition, which in return would drive down the prices again.⁴⁴ The effects of competition on pharmaceutical prices can be best observed after a patent expires when generic products enter the markets, regularly leading to significant reductions of drug prices by up to 80 percent.⁴⁵ This can be further exemplified when considering that by producing HIV/AIDS drugs in its own government laboratories in the early 2000s, Brazil managed to reduce the treatment costs by an average of 70 percent.⁴⁶ Furthermore, the introduction of generics not only provides for cheaper off-brand products, but commonly leads to a reduction of the prices offered by originator

³⁸ TRIPS Agreement (n 37) Article 7; ECOSOC (n 4) paras 16 and 23.

³⁹ ECOSOC (n 4) para 23.

⁴⁰ Flynn S, Hollis A and Palmedo M (n 14) 186.

⁴¹ cf. Abbott FM, 'Trade in Medicines' (n 8) 124; Forman L, 'From TRIPS-Plus to Rights Plus? Exploring Right to Health Impact Assessment of Trade-Related Intellectual Property Rights through the Thai Experience' (2012) 7 AJWH 347, 349.

⁴² cf. Hestermeyer H (n 1) 138-142.

⁴³ Henry D and Searles A (n 15) 9.3.

⁴⁴ *ibid.*

⁴⁵ Dutfield G, 'Healthcare Innovation and Patent Law's' (n 4) 453; Dutfield G, *Intellectual Property Rights and the Life Science Industries: Past, Present and Future* (2nd edn, World Scientific 2009) 27; Hestermeyer H (n 1) 148; Michelsohn A, 'To Make Healthcare More Affordable, Fight Drug Patent Abuse with a Fury' (*IP Watchdog*, 14 March 2018) <<https://www.ipwatchdog.com/2018/03/14/make-healthcare-affordable-fight-drug-patent-abuse/id=94731/>> accessed 23 April 2018.

⁴⁶ ECOSOC (n 4) para 57; Hestermeyer H (n 1) 148.

companies as well.⁴⁷ The combined effect of this can be tremendous. By 2006 Brazil managed to reduce the annual treatment costs of HIV/AIDS patients from \$10,439 to \$132 for its generic drugs, with the price of the branded version dropping to \$556.⁴⁸ It can thus be seen that by preventing competition, patents are a principal determinant of high drug prices.⁴⁹

By granting exclusive rights to inventors, patents provide the basis for pricing drugs above their competitive market value, thereby limiting the accessibility of novel medicines for the poor.⁵⁰ Given that the very concept of patents is designed to strengthen the market position of originator companies, the research-based pharmaceutical industry is enabled to set high prices for patented drugs almost freely.⁵¹ When further considering that profit maximisation is one of the fundamental purposes of corporations, it becomes apparent that there is little reason for patent holders to reject the possibility of setting high prices.⁵² Evidence for the correlation between patents and price increases above the competitive market value can be examined when drawing attention to the case of Malaysia, where between 1999 and 2005, following the introduction of pharmaceutical patentability, the prices of medicines increased on average by 28 percent per year.⁵³ Similarly, in a cross-border study from 2007, Borrell revealed that drug bundles for the treatment of HIV/AIDS which include at least one patented pharmaceutical, are on average 70 percent more expensive than drug bundles that only consist of generic copies.⁵⁴ In a report from 2001, the UN Commission on Human Rights highlighted that 150 milligrams of the HIV drug Flucanazole cost \$697 in Malaysia, \$703 in Indonesia, and \$817 in the Philippines, while India, where Flucanazole was not patented, kept the price as low as \$55.⁵⁵

In monopolistic market positions, corporations are commonly enabled to set prices freely without regard to competition, which, due to the limited choices left for

⁴⁷ Henry D and Searles A (n 15) 9.9.

⁴⁸ *ibid.*

⁴⁹ Forman L (n 41) 351.

⁵⁰ Abbott FM, 'Trade in Medicines' (n 8) 120; Abbott FM, 'Intellectual Property and Public Health' (n 14) 9; Hestermeyer H (n 1) 149; Borrell JR, 'Pricing and Patents of HIV/AIDS Drugs in Developing Countries' (2007) 39 *Applied Economics* 505, 506.

⁵¹ Abbott FM, 'Trade in Medicines' (n 8) 134; Hestermeyer H (n 1) 138; Hunt P and others, *Neglected Diseases: A Human Rights Analysis* (WHO 2007) 35.

⁵² Hestermeyer H (n 1) 150-151.

⁵³ Forman L (n 41) 351.

⁵⁴ Borrell JR (n 50) 514.

⁵⁵ ECOSOC (n 4) para 44.

consumers, commonly leads to higher prices.⁵⁶ Corporations are generally enabled to increase prices until they reach a level where the number of customers unwilling to pay high prices ultimately reduces profitability.⁵⁷ Thus, for regular types of products, corporations are prevented from charging unreasonably high prices as consumers can simply decide not to acquire products which they consider to be too expensive.⁵⁸ In the field of pharmaceuticals, however, the situation is rather different and more problematic. Notably, corporations can charge considerably higher prices the more inelastic the demand for a product is.⁵⁹ As can be expected, the demand for medications is commonly relatively inelastic as patients are willing to pay extensive prices in order to protect their life and health.⁶⁰ The price elasticity is therefore directly connected to the essential nature of medicines, meaning that the more essential a medicine is, the more consumers are willing to pay. For the most essential medications, consumers are willing to pay almost anything, as long as they can afford it.⁶¹ Thus, the prices of essential medicines are also relatively inelastic to income levels, suggesting that patients only cease to buy such medications when they run out of resources.⁶² Furthermore, prices tend to go even higher for patented products which do not have any close substitutes, as this puts corporations in a strong market position in which they can exercise true monopoly power.⁶³

Monopolists can generally choose from two different distribution strategies: (1) producing and selling large quantities of a product at a low margin, or (2) limiting the output and selling low quantities at a high margin.⁶⁴ Manufacturers will commonly employ the strategy that expectedly generates the highest overall profits.⁶⁵ Particularly in the field of pharmaceuticals, this tends to lead to higher drug prices as due to the inelastic demand curve, low volume sales at high prices regularly generate the highest profit margins.⁶⁶ Patented medicines are thus not priced in a way that recoups competitive market returns plus the R&D costs, but rather follow the industry's interest

⁵⁶ cf. Henry D and Searles A (n 15) 9.2 and 9.6.

⁵⁷ Flynn S, Hollis A and Palmedo M (n 14) 186.

⁵⁸ *ibid* 187.

⁵⁹ *ibid* 186.

⁶⁰ Hestermeyer H (n 1) 140 and 145; Henry D and Searles A (n 15) 9.3.

⁶¹ Henry D and Searles A (n 15) 9.2.

⁶² *ibid* 9.3; Hestermeyer H (n 1) 140; Flynn S, Hollis A and Palmedo M (n 14) 188-189.

⁶³ Abbott FM, 'Intellectual Property and Public Health' (n 14) 9; Henry D and Searles A (n 15) 9.4 and 9.8; Hestermeyer H (n 1) 143; Flynn S, Hollis A and Palmedo M (n 14) 188.

⁶⁴ Hestermeyer H (n 1) 143.

⁶⁵ *ibid*.

⁶⁶ cf. *ibid* 144.

in increasing prices until they reach the maximal possible profitability.⁶⁷ In effect, this has a substantial adverse impact on society as a so-called ‘deadweight loss’ is created, meaning that a large number of consumers are excluded as they cannot afford the products.⁶⁸ Thus, patients who would be able to be cured at lower medicine costs are prevented from receiving available treatment.⁶⁹ Therefore, in the field of pharmaceuticals, the term ‘deadweight loss’ has a particularly cynical ring to it, as human lives are literally falling victim to high medicine prices.⁷⁰

Where patents lead to unrestricted monopoly positions, the system completely fails to account for substantial wealth inequalities and severe poverty, and the implications on public health in developing countries. This can be illustrated by reference to the HIV/AIDS crisis in sub-Saharan Africa, where in the early 2000s Antiretroviral (ARV) therapies were offered at basically the same prices that were charged in industrialised OECD countries.⁷¹ In other words, ARVs were priced out of reach for the poor, with only 7% of the population in developing countries being able to afford them.⁷² Counter-intuitively, purely economic monopolistic pricing strategies may actually lead to higher prices for medicines in developing countries than in industrialised markets.⁷³ In 2009, for example, the price of the drug Stavudine in low-income countries was 37 percent higher than in middle-income countries.⁷⁴ The reason for such a seemingly illogical pricing strategy is that in many developing countries, and particularly in LDCs, there exists an extreme inequality in the distribution of wealth in that large sectors of the population live in severe poverty, while the much smaller and wealthier part of the population can have incomes similar to those of the wealthy in industrialised nations.⁷⁵ A middle class is basically non-existent and can be ignored in pricing considerations. In such markets, it can be more profitable for the pharmaceutical industry to set prices that only the wealthiest can afford.⁷⁶ Flynn, Hollis and Palmedo show in a 2009 study that in markets with high levels of income inequality the highest

⁶⁷ Henry D and Searles A (n 15) 9.10.

⁶⁸ Hestermeyer H (n 1) 144; Lucyk S (n 6) 207; Turk M (n 29) 1000.

⁶⁹ Flynn S, Hollis A and Palmedo M (n 14) 186.

⁷⁰ *ibid*; Lucyk S (n 6) 207.

⁷¹ Abbott FM, ‘WTO TRIPS Agreement and its Implications’ (n 33) 5.

⁷² Byrne S and others, ‘Patent Rights or Patent Wrongs? The Case of Patent Rights on AIDS Drugs’ (2006) 15 *Bus. Ethics Eur. Rev* 299, 300.

⁷³ Hestermeyer H (n 1) 146; Flynn S, Hollis A and Palmedo M (n 14) 190.

⁷⁴ Henry D and Searles A (n 15) 9.10.

⁷⁵ Flynn S, Hollis A and Palmedo M (n 14) 190.

⁷⁶ *ibid* 186 and 189-190; Hestermeyer H (n 1) 146.

pharmaceutical profits are achieved when prices are set to a level which only the wealthiest 10 percent can afford, as the few rich people can spend more on medications than the entire poor population combined.⁷⁷ Conversely, in industrialised nations the highest profits are commonly achieved when prices are set to a level where both the highest income class as well as the middle class can afford the products.⁷⁸ The availability of health insurances, as large-scale buyers in monopsony⁷⁹ positions, and price controls, further ensure that certain price levels can be maintained.⁸⁰ In the developed world, corporations thus can achieve the highest profit margins when drugs are sold at a slightly lower price to a substantially larger group of the population, as there exists a sufficiently sized middle-class.⁸¹ In Norway, for example, the highest profits are realised at a price that all but the poorest 20 percent can afford.⁸²

This is particularly problematic as most people in developing countries do not have health insurance, meaning 90 percent of the population are left without access to patented medicines.⁸³ A theoretical solution to this problem would be the consideration of price discriminations within a market, whereby the pharmaceutical industry could receive higher profits from the wealthy population while at the same time ensuring the affordability of medicines for the poor. In reality, however, discounted prices are commonly negotiated by large volume purchasers, such as health insurances. As in developing countries most people living in poverty are not covered by health insurances, the price reductions would only benefit the wealthy population while doing little for the poor.⁸⁴

As can be seen, the overall implication of pharmaceutical patentability is an increase in medicine prices due to the restricted and delayed availability of cheaper generic alternatives, which comes at a substantial human cost.⁸⁵ The prices of medications directly determine whether patients can afford required medications, with lower prices

⁷⁷ Flynn S, Hollis A and Palmedo M (n 14) 189-190.

⁷⁸ *ibid* 190.

⁷⁹ A monopsony can be described as a buyer's monopoly; i.e. there is only one major buyer. See thereto: Oxford Living Dictionaries, 'Monopsony' <<https://en.oxforddictionaries.com/definition/monopsony>> accessed 21 March 2019.

⁸⁰ cf. Henry D and Searles A (n 15) 9.14-9.18.

⁸¹ Flynn S, Hollis A and Palmedo M (n 14) 190.

⁸² *ibid* 190.

⁸³ *ibid* 189; Reichman JH (n 10) 254.

⁸⁴ Flynn S, Hollis A and Palmedo M (n 14) 191; Ho CM, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (OUP 2011) 250; Reichman JH (n 10) 254.

⁸⁵ Abbott FM, 'WTO TRIPS Agreement and its Implications' (n 33) 4; Forman L (n 41) 353.

allowing for more patients receiving treatment while higher prices restrict access to treatment.⁸⁶ Furthermore, while the majority of the drugs included on the WHO's List of Essential Medicines are off-patent, there are a small number of essential medicines on the list which are relatively new and will enjoy patent protection for a number of years to come before cheaper generics become available.⁸⁷ A problem of the WHO List of Essential Medicines is that it is drafted with regard to budgetary restrictions, so that, according to Abbott, there is a reasonable concern that certain essential medicines are excluded specifically because of their high prices resulting from patent rights.⁸⁸ In summary, it can be observed that, especially in developing countries, the accessibility of medicines is severely affected by patents, with patented medications regularly being priced above affordability for large sectors of the world's population, preventing patients from accessing treatment for, at times, life-threatening conditions.⁸⁹

The already concerning situation is further aggravated by other IP provisions alongside patent protection. In particular, the protection of test and other data through data exclusivity provisions can further delay the introduction of cheaper generic alternatives by preventing generic manufacturers from using existing clinical test data submitted by the originator company for the marketing approval of generics.⁹⁰ Furthermore, the protection of test data can provide exclusive protection for products that do not meet patentability requirements, as data exclusivity protection cannot be challenged, in the way that patents can be challenged, for a failure to make an adequate contribution to science.⁹¹ As a result, the market entry of generic medicines is either delayed until after data exclusivity periods expire, or generic manufacturers are required to conduct their own clinical trials, which, as elaborated above in chapter 2.4.4, is ethically questionable and would furthermore increase the prices of the generics due to additional research costs.

Similarly, patent linkage provisions, which are regularly included in TRIPS-Plus FTAs, enable patent owners to block the marketing approval of generic versions of

⁸⁶ Abbott FM, 'WTO TRIPS Agreement and its Implications' (n 33) 8; Hunt P and others, *Neglected Diseases* (n 51) 33.

⁸⁷ Abbott FM, 'Trade in Medicines' (n 8) 123; Abbott FM, 'Intellectual Property and Public Health' (n 14) 7-8; Hestermeyer H (n 1) 150.

⁸⁸ Abbott FM, 'Intellectual Property and Public Health' (n 14) 7-8.

⁸⁹ *ibid* 8; Cullet P (n 2) 151; Forman L (n 41) 350.

⁹⁰ Abbott FM, 'Trade in Medicines' (n 8) 120; Henry D and Searles A (n 15) 9.9.

⁹¹ Abbott FM, 'Trade in Medicines' (n 8) 127-128.

their patented drugs.⁹² Thereby, patent owners can, in principle, negate the value of compulsory licenses that address public health emergencies. While a generic drug can be produced under a compulsory license, it also requires marketing approval before it can be brought into circulation. By making use of a patent linkage provision, a patent holder can prevent the marketing approval of the generic drug produced under a compulsory license, for as long as the product is patented.⁹³ It can thus be seen that patent linkage provisions can hamper the market entry of affordable medications, even where patent provisions directly provide for exceptions for the protection of public health.⁹⁴

All things considered, it can be submitted that pharmaceutical patents in particular, and international IP law more generally, severely restrict the affordability and accessibility of medical products by excluding competition which is an essential requirement for lowering medicine prices.⁹⁵

4.2.3 Balancing Mechanisms under TRIPS and TRIPS-Plus Standards

As can be seen in the above analysis, patents generate both positive and negative net effects. From a general human rights perspective, it can be regarded as positive that patents promote property rights by protecting the interests of authors and creators of IP. Similarly, patents promote development by providing an incentive for the R&D of new products. In the field of pharmaceuticals, however, the mechanics of patents lead to a considerable controversy. On the one hand, patents contribute to the accessibility of medicines by providing the aforementioned incentives for innovation in the field of pharmaceuticals. On the other hand, patents can create severe obstacles, restricting the accessibility of medicines by increasing the prices of patented drugs to levels which the majority of the world's population simply cannot afford.⁹⁶ It is therefore crucial to

⁹² *ibid* 121.

⁹³ *ibid*; Smith RD, Correa C and Oh C (n 19) 687-688; Xiong P, 'Patents in TRIPS-Plus Provisions and the Approaches to Interpretation of Free Trade Agreements and TRIPS: Do They Affect Public Health?' (2012) 46 *Journal of World Trade* 155, 172.

⁹⁴ *cf.* Abbott FM, 'Trade in Medicines' (n 8) 121.

⁹⁵ Smith RD, Correa C and Oh C (n 19) 688; Henry D and Searles A (n 15) 9.9.

⁹⁶ Cullet P (n 2) 143.

acknowledge that pharmaceutical patents can only be justified if the research incentive provided is adequately balanced with the public health interest of the population in having affordable access to required medications. Achieving this balance, however, is particularly intricate as the importance of the affordability of today's existing medicines has to be weighed against the importance of the availability of new medications in the future, with both sides having direct implications for the enjoyment of the human rights to health and life.⁹⁷ One approach to striking a balance is briefly mentioned in Article 7 TRIPS, calling for a balance of rights and obligations.⁹⁸ As TRIPS however, does not provide any further details as to how such a balance can be achieved,⁹⁹ the following analysis will scrutinise how far the international patent regime actually provides for establishing the required adequate balance.

In this regard, it may be suggested that the TRIPS flexibilities can be utilised to minimise the adverse impacts of patents on the accessibility of medicines.¹⁰⁰ Thus, the flexibilities provided for may be regarded as a means for achieving a balance. In reality, the TRIPS flexibilities have turned out to be the only remaining leeway for governments seeking to provide more affordable medical treatment.¹⁰¹ Furthermore, the applicability of the flexibilities, as well as the interpretation of their exact scope, are not clarified, so that an adequate utilisation of these flexibilities requires skilled legal negotiations. Developing countries, however, commonly have a deficit in the high skills required to ensure that the flexibilities can be implemented in their best interests.¹⁰² Thus, even though the TRIPS Agreement provides for flexibilities, conflicts between human rights and the international patent regime remain unresolved and of considerable concern.¹⁰³

More generally speaking, while explicitly referred to in the objectives and purposes of TRIPS, the protection of public interests only finds minor consideration in the specific IP provisions of the agreement, and is seemingly relegated to constituting an exclusion to the applicable rule. In particular, the public interest is merely addressed by the

⁹⁷ Hestermeyer H (n 1) 158.

⁹⁸ TRIPS Agreement (n 37) Article 7.

⁹⁹ ECOSOC (n 4) para 23.

¹⁰⁰ Helfer LR, 'Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking' (2004) 29 *Yale Journal of International Law* 1, 43.

¹⁰¹ Forman L (n 41) 351.

¹⁰² Richards DG (n 32) 277.

¹⁰³ cf. Helfer LR (n 100) 49.

exceptions and flexibilities of the agreement's IP sections, rather than being a concern of the treaty's main provisions.¹⁰⁴ This stands in stark contrast to the very idea of human rights, which strive to always focus on the public societal interests.¹⁰⁵ While it seems positive that under TRIPS deviations from the general patent rules to address public health issues are permissible, from a human rights perspective this approach is insufficient.¹⁰⁶ The importance of human dignity is such that the realisation of the human rights to health and life cannot be adequately achieved as a mere exception to private property rights.¹⁰⁷ Thus, a human rights approach to IP would place concerns about the protection of human rights at the centre of a patent regime, i.e. in the main provisions of an agreement rather than only in its exceptions.¹⁰⁸ Furthermore, according to Guan, the TRIPS Agreement has an inherent 'birth defect' which is to be seen in the insubstantial idea that public interests such as health concerns can be adequately promoted through a private rights regime that provides for market exclusivity.¹⁰⁹ In this regard, Richards rightly points out that a solution to the issues surrounding the accessibility and affordability of medical products is unlikely to be found in 'market solutions'.¹¹⁰

Consequently, it comes as no surprise that when taking a deeper look at the exceptions and flexibilities provided by the TRIPS Agreement, particularly the way its system of compulsory licensing works, a number of flaws become apparent. First and foremost, it must be acknowledged that the availability of compulsory licensing in general is beneficial as it provides a mechanism for taking measures for the protection of public health. When successfully utilised, compulsory licenses can substantially enhance access to medicines. In Thailand, for example, the use of compulsory licenses increased access to Efavirenz four-fold between 2006 and 2008, from 5000 people receiving treatment to 20000, and access to Lopinavir-Ritonavir increased more than ten-fold, from under 300 persons receiving treatment to 3000 persons.¹¹¹ Similarly, the use of compulsory licenses on Efavirenz in Malaysia reduced the drug's price by two

¹⁰⁴ Cullet P (n 2) 152; ECOSOC (n 4) para 22.

¹⁰⁵ Cullet P (n 2) 152.

¹⁰⁶ *ibid* 155.

¹⁰⁷ *ibid*.

¹⁰⁸ ECOSOC (n 4) para 22.

¹⁰⁹ Guan W (n 36) 411.

¹¹⁰ Richards DG (n 32) 278.

¹¹¹ Forman L (n 41) 368.

thirds.¹¹² Furthermore, Thailand's use of compulsory licenses led to a global reduction of prices of the patented drugs.¹¹³ Nevertheless, compulsory licenses cannot be regarded as the ultimate solution to the public health issues faced by developing countries, which are aggravated by the international patent regime.¹¹⁴

According to Forman, it is inadequate to refer to compulsory licenses as a TRIPS flexibility, as there is nothing flexible about the system that facilitates their use.¹¹⁵ One of the main problems with compulsory licensing under international patent laws is that its use regularly becomes a political issue, rather than a purely legal one, and that countries which grant compulsory licenses may face political and economic sanctions.¹¹⁶ A further flaw of the compulsory licensing provisions of TRIPS is that the agreement does not sufficiently define the exact scope of the requirement to provide adequate remuneration to the patent holder.¹¹⁷ This introduces a further problem to the exceptions of the TRIPS Agreement. On the one hand, a remuneration that is set too high artificially increases the price of a generic drug produced under a compulsory license. On the other hand, if the remuneration is too low, the research-based industry loses out on profits and may thereby be discouraged from conducting further expensive pharmaceutical research.¹¹⁸ For this reason, compulsory licenses that safeguard the affordability of medicines may be regarded as an obstacle to innovation, on the grounds that when the pharmaceutical industry is exposed to the risk of excessive use of compulsory licenses, corporations have no incentive for being innovative.¹¹⁹ According to Phillips, compulsory licenses therefore constitute a direct threat to the development of new medical products.¹²⁰

Accordingly, while the use of compulsory licenses as an exception to patents in order to address urgent health concerns generally seems reasonable, a systematic use of this flexibility can have negative impacts on innovation.¹²¹ Thus, any decision on the

¹¹² Smith RD, Correa C and Oh C (n 19) 689.

¹¹³ Forman L (n 41) 368-369.

¹¹⁴ Bernieri RC, 'Intellectual Property Rights in Bilateral Investment Treaties and Access to Medicines: The Case of Latin America' (2006) 9 JWIP 548, 556.

¹¹⁵ Forman L (n 41) 351.

¹¹⁶ cf. Abbott FM, 'Trade in Medicines' (n 8) 131.

¹¹⁷ *ibid.*

For an analysis of the compulsory licensing system under TRIPS, see chapters 2.4.3.7 and 2.4.3.8.

¹¹⁸ Flynn S, Hollis A and Palmedo M (n 14) 185.

¹¹⁹ cf. Reichman JH (n 10) 257.

¹²⁰ Phillips AA (n 5) 412.

¹²¹ Flynn S, Hollis A and Palmedo M (n 14) 185.

granting of a compulsory license requires the balancing of public health interests now, with the public health interests of the future.¹²² It is submitted, however, that compulsory licenses granted in developing countries only have minor impacts on the overall research incentives for medications for diseases that affect both developing countries and industrialised countries, as the pharmaceutical industry commonly recoups its research costs in wealthy markets.¹²³ Furthermore, as compulsory licenses can bring about substantial benefits for the public health situation in developing countries, their use is particularly justified in markets where patented medicine prices are set to a level which only the wealthiest class of the population can afford, as discussed above in 4.2.2.¹²⁴

Another inherent problem of the initial compulsory licensing system under TRIPS, i.e. how to legally supply developing countries that do not have adequate pharmaceutical production capacity with the generic drugs produced under a compulsory license, was addressed by a waiver decision that ultimately led to an amendment of the TRIPS Agreement with the purpose of improving the compulsory licensing system. After conducting an analysis of the waiver system in chapter 2.4.3.8, however, it becomes apparent that the TRIPS Amendment is not sufficient to improve the balance between private IP rights and the public interest in health, but rather creates new obstacles.¹²⁵ According to Guan, the waiver creates a segmentation of the compulsory licensing system by limiting its scope of applicability and the countries that can benefit from the system.¹²⁶ The TRIPS amendment thereby exacerbates barriers to the utilisation of compulsory licenses which undermines the flexibility the system should have provided under the initial TRIPS Agreement.¹²⁷ This stands in stark contrast to the agreement's objectives and purposes.¹²⁸

The imbalances of the international patent regime, arguably may be a reflection of the power imbalances between the negotiating parties, i.e. between developing countries

¹²² *ibid.*

¹²³ *ibid* 192.

¹²⁴ *ibid* 185.

¹²⁵ Gumbel M, 'Is Article 31*bis* enough? The Need to Promote Economies of Scale in the International Compulsory Licensing System' (2008) 22 *Temple Int'l & Comp. L. J.* 161, 177.

¹²⁶ Guan W (n 36) 433 and 439.

¹²⁷ *ibid* 433-434; Gumbel M (n 125) 177.

¹²⁸ Guan W (n 36) 434.

as net importers of IP and industrialised countries as net producers of IP.¹²⁹ Such imbalances of power become particularly apparent when considering how pressure exercised by industrialised countries has led to restrictions of the use of TRIPS flexibilities and exceptions in developing countries.¹³⁰ These pressures are commonly manifested in one of two ways. Firstly, patent holding corporations that feel unjustly deprived of their exclusive rights may threaten to, or actually withdraw products from the national markets of countries that make use of the exceptions provided for by TRIPS. This happened, for example, in 2007 after Thailand granted a compulsory license on Lopinavir+Ritonavir, marketed as Kaletra, when the patent holder, Abbott Laboratories, decided to retaliate against the use of the compulsory license by withdrawing its new medicines from the Thai market.¹³¹

Secondly, there is the possibility of direct political and economic threats made by the governments of countries where patent holders are based.¹³² This, again, can be exemplified by reference to Thailand's experiences, where US pressure led to Thailand implementing an IP system in full compliance with the TRIPS requirements by the early 2000s, neglecting its right to make use of the transition periods provided for developing countries, and the extensions thereto.¹³³ Furthermore, Thailand faced threatening political objections by the EU, against its use of compulsory licensing to increase access to HIV/AIDS and coronary disease treatments, which was perfectly legal under TRIPS and the Doha Declaration.¹³⁴ It should be noted that such governmental pressure is not only unlawful under WTO rules, but further seems to stand in contradiction to the human rights obligation of states to cooperate and provide international assistance to facilitate the realisation of the right to health in developing countries.¹³⁵ The same can be said in regard to pressure exercised by industrialised nations in FTA negotiations, pushing developing countries to relent to accepting ever increasing TRIPS-Plus patent standards which are detrimental to public health concerns.

¹²⁹ Sell SK, 'TRIPS-Plus Free Trade Agreements and Access to Medicines' (2007) 28 *Liverpool Law Review* 41, 58.

¹³⁰ cf. Forman L (n 41) 359. See thereto: chapters 2.4.3.7 and 2.4.3.8, and chapters 2.5.1.4 and 2.5.1.5.

¹³¹ Forman L (n 41) 368.

¹³² Abbott FM, 'Intellectual Property and Public Health' (n 14) 12.

¹³³ Forman L (n 41) 359.

¹³⁴ Abbott FM, 'Intellectual Property and Public Health' (n 14) 12.

¹³⁵ Hunt P and others, *Neglected Diseases* (n 51) 37.

This trend of developed countries exercising their power was already observed throughout the initial TRIPS negotiations, where, according to Abbott, developing countries were basically forced to accept the high IP provisions through the ‘take it or leave it’ approach offered at the establishment of the WTO.¹³⁶ In this way, the developed world prevented developing countries from implementing an IP system that adequately accounts for their needs and current degree of development.¹³⁷ Where increased IP standards, particularly in TRIPS-Plus FTAs, are in fact forced upon developing countries, it must be brought into question whether those standards can actually be regarded as legitimate.¹³⁸ According to a statement of then French president Chirac in 2004, forcing TRIPS-Plus standards on developing countries is comparable to immoral blackmail.¹³⁹ Ultimately, while Article 1(1) TRIPS enables member states to adopt higher standards of IP protection, it also provides that members may not be obliged to do so.¹⁴⁰

As the TRIPS Agreement itself establishes high levels of patent protection, there seems to be little rationale for introducing even stronger protection, particularly in developing countries where the patentability of pharmaceuticals under TRIPS already has severe impacts on the public health situation.¹⁴¹ Particularly in consideration of the deadweight loss created by pharmaceutical patents, the 20-year minimum protection period established by TRIPS seems quite extensive, but may be regarded by society as a necessary trade-off to incentivise further pharmaceutical research.¹⁴² Any increase of this protection term through TRIPS-Plus standards, however, inadequately shifts the balance towards the protection of private interests, and seems therefore unjustified in view of the resulting adverse impacts on human health and life.¹⁴³

At the same time, while providing clearly defined minimum standards of protection, the TRIPS Agreement fails to define any upper limits that ensure that protection

¹³⁶ Abbott FM, ‘WTO TRIPS Agreement and its Implications’ (n 33) 1.

¹³⁷ Dutfield G and Suthersanen U, ‘Harmonisation or Differentiation in Intellectual Property Protection? The Lessons of History’ (2005) 23 *Prometheus* 131, 131.

¹³⁸ Frankel S (n 37) 1025.

¹³⁹ Morin JF, ‘Tripping up TRIPS Debates IP and Health in Bilateral Agreements’ (2006) 1 *Int. J. Intellectual Property Management* 37, 51.

¹⁴⁰ TRIPS Agreement (n 37) Article 1(1); Frankel S (n 37) 1032.

¹⁴¹ Smith RD, Correa C and Oh C (n 19) 688.

¹⁴² Flynn S, Hollis A and Palmedo M (n 14) 188.

¹⁴³ *ibid.*

standards are kept in a certain balance.¹⁴⁴ Thus, it may be argued that under TRIPS, industrialised nations cannot be prevented from pushing for ever increasing levels of IP protection in FTAs to the detriment of developing countries.¹⁴⁵ This problem was not eliminated through the Doha Declaration, which, while providing guidance on how a balance between patent rights and the public interest in health can be achieved, does not provide any upper limits of IP protection either.¹⁴⁶ It follows that while the Doha Declaration and the resultant amendment of the TRIPS Agreement provide safeguards and flexibilities that can be used to protect public health, WTO member states remain free to adopt higher IP standards and restrictions of the flexibilities in bilateral and multilateral trade agreements.¹⁴⁷ The Doha Declaration, nevertheless, constitutes a crucial reaffirmation of the need to balance IP rights and the public interest, and the importance of maintaining the TRIPS flexibilities to achieve this.

Article 1(1) TRIPS, furthermore, establishes that voluntarily implemented higher protection standards than those provided for by TRIPS must ‘not contravene the provisions of this Agreement.’¹⁴⁸ It is submitted here, that this has to include the objectives and purposes of the agreement, as well as the Doha Declaration which reinforces the importance of public health as a basic principle of TRIPS under Article 8. It is therefore false to suggest that nothing in the TRIPS Agreement can prevent an unrestricted proliferation of IP protection levels. The conception that higher IP protection is generally legitimate is thus oversimplified, as TRIPS-Plus standards that do not comply with the agreement’s objectives and regulations are inconsistent with TRIPS, and may, according to Frankel, constitute a violation thereof.¹⁴⁹ Accordingly, it can be suggested that TRIPS-Plus FTAs need to pay due regard to the objectives and purposes of TRIPS in order to be legitimate.¹⁵⁰ This point of view, however, is not uncontroversial, as it may be argued that TRIPS-Plus provisions constitute *lex specialis*, which under international law prevail over the *lex posterior* rules of the TRIPS Agreement.¹⁵¹ Conversely, I suggest that this may not hold true where such

¹⁴⁴ UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (CUP 2005) 35; Xiong P (n 93) 175.

¹⁴⁵ Gumbel M (n 125) 171; UNCTAD-ICTSD (n 144) 35.

¹⁴⁶ Morin JF (n 139) 51.

¹⁴⁷ cf. Gumbel M (n 125) 171.

¹⁴⁸ TRIPS Agreement (n 37) Article 1(1); Frankel S (n 37) 1033.

¹⁴⁹ Frankel S (n 37) 1036 and 1041.

¹⁵⁰ *ibid* 1039.

¹⁵¹ Xiong P (n 93) 181.

TRIPS-Plus provisions directly violate the objectives and purposes of the TRIPS Agreement.

TRIPS-Plus Agreements can be considered as a simple continuation of the long-standing trend in international law, striving for ever increasing IP rights.¹⁵² Protection under TRIPS is simply regarded by industrialised nations and the pharmaceutical industry as the bare minimum, rather than as an adequate standard of protection.¹⁵³ Imposing stricter, first-world IP protection levels on all countries alike, including poverty stricken developing countries, however, does not take account of the particular needs of each individual country.¹⁵⁴ Increases in IP protection in TRIPS-Plus FTAs, including patent term extensions and relaxed patentability standards, ultimately lead to an increased amount of patented medicines with direct negative implications on the affordability of drugs and the number of people who receive treatment.¹⁵⁵ Additionally, by providing restrictions to the exceptions and flexibilities of TRIPS, TRIPS-Plus standards erode the already limited balancing mechanisms, and thereby shift the balance even more towards the protection of private economic interests.¹⁵⁶ It is thus suggested that TRIPS-Plus standards are frequently inconsistent with the obligations of governments under the right to health, because human rights and public health concerns are often neglected in TRIPS-Plus negotiations.¹⁵⁷ If FTAs take public health into consideration at all, the issue is frequently addressed in side letters with unclear legal standing, which are therefore, inadequate for providing reliable flexibility.¹⁵⁸

In summary, it can be noted that TRIPS-Plus standards are particularly unsuitable for developing countries, as they shift the balance away from public health concerns towards a proliferation of IP protection, without adding any benefits. This can be derived from the fact that the supporters of TRIPS-Plus standards commonly claim

¹⁵² Grosse Ruse-Khan H, 'The International Law Relation between TRIPS and Subsequent TRIPS-Plus Free Trade Agreements: Towards Safeguarding TRIPS Flexibilities?' (2011) 18 J Intell. Prop. L. 325, 328-329.

¹⁵³ *ibid* 329.

¹⁵⁴ Morin JF (n 139) 44.

¹⁵⁵ Dutfield G, 'Healthcare Innovation and Patent Law's' (n 4) 454; Ho CM (n 84) 251.

¹⁵⁶ Abbott FM and Reichman JH, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 JIEL 921, 926; Dutfield G, 'Healthcare Innovation and Patent Law's' (n 4) 454; Forman L (n 41) 351; Xiong P (n 93) 172.

¹⁵⁷ Forman L (n 41) 349; Xiong P (n 93) 176.

¹⁵⁸ Abbott FM, 'Trade in Medicines' (n 8) 121.

that they bring about similar benefits to those that the initial TRIPS Agreement should have achieved. These include enhanced research incentives and increased FDI in developing countries, which, as shown in the second section of this chapter below, have not even been approximately realised under TRIPS.¹⁵⁹ It can thus be concluded that TRIPS-Plus standards that aggravate problems of the accessibility of medicines for the sake of industry profits are unethical and cannot be justified.¹⁶⁰

4.2.4 Concluding Controversy

Generally speaking, it is suggested by Abbott that currently there is no uniformly accepted model providing guidance on how an adequate balance between private economic rights and public health can be established.¹⁶¹ Neither is there an easy approach to balancing the affordability of medicines now with the availability of new medicines in the future.¹⁶² In its most basic form, however, a balanced approach to pharmaceutical patentability would provide protection standards that are strong enough to create real research incentives, while at the same time not being so strong that they generate obstacles to the accessibility of medicines, or become obstacles to innovation themselves.¹⁶³ As seen above, however, there currently exists an imbalance leaning towards to the protection of private rights.¹⁶⁴ Additionally, the rights of IP owners and their responsibilities are in a severe disequilibrium towards one another, as the responsibilities are rarely defined by international IP laws.¹⁶⁵ Thus, a major problem with market mechanisms more generally is that they provide rewards for successful economic actors, while paying little regard to the distribution of public goods, such as health.¹⁶⁶ Health, however, is a basic human need which should not be subject to purely economic considerations.¹⁶⁷

¹⁵⁹ Ho CM (n 84) 249.

¹⁶⁰ cf. Lopert R and Gleeson D, 'The High Price of "Free" Trade: U.S. Trade Agreements and Access to Medicines' (2013) 41 J Law Med Ethics 199, 208 and 210.

¹⁶¹ Abbott FM, 'Trade in Medicines' (n 8) 118.

¹⁶² *ibid.*

¹⁶³ Dutfield G, 'Healthcare Innovation and Patent Law's' (n 4) 467-468.

¹⁶⁴ Forman L (n 41) 369.

¹⁶⁵ Trouiller P and others, 'Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure' (2002) 359 The Lancet 2188, 2193.

¹⁶⁶ de Feyter K, *Human Rights: Social Justice in the Age of the Market* (Zed Books 2005) 13.

¹⁶⁷ Cullet P (n 2) 141.

It must be noted here that pharmaceutical patents, and IP rights more generally, are not the only issues that negatively affect the accessibility of medications, and that a variety of factors contribute to the occurrence of unaffordable medicine prices.¹⁶⁸ While these other factors – which include, *inter alia*, poverty, infrastructure, taxes, administration costs, *et cetera* – can undoubtedly have serious negative impacts on the accessibility of medicines, patents nevertheless constitute a significant determinant of the prices of pharmaceutical products, with direct impacts on the affordability and distribution of drugs.¹⁶⁹

While the TRIPS Agreement provides for flexibilities and exceptions that can be utilised to at least avert some of the detrimental impacts of IP rights on public health, these mechanisms are not frequently applied by developing countries for fear of trade sanctions and retaliations by the private business sector.¹⁷⁰ This is particularly unfortunate, as the Brazilian experience, as discussed above in 4.2.2, proves that TRIPS can theoretically be implemented in a way that strikes a relatively adequate balance which pays due regard to public health concerns.¹⁷¹ TRIPS-Plus standards, on the other hand, tend to further frustrate these last remaining balancing mechanisms, which seems completely unjustifiable in light of the Doha Declaration.¹⁷² The Doha Declaration provides an explicit reaffirmation of the right of governments to apply the exceptions and flexibilities of TRIPS for the protection of public health, wherefore I suggest that the Doha Declaration must always constitute the absolute minimum safeguard of the right to health in order for medical patents to be justifiable.

Nonetheless, the modern international patent regime is particularly inclined towards the protection of the economic interests of the research-based industry, which reflects a seemingly one-sided view in which research incentives are attributed more importance than the protection of public welfare against concomitant losses.¹⁷³ And while the pharmaceutical industry has a long established place amid the most profitable technological sectors, patent holders in developed countries continue to push for higher

¹⁶⁸ *ibid* 143; ECOSOC (n 4) para 43; Forman L (n 41) 350; Hestermeyer H (n 1) 151.

¹⁶⁹ Abbott FM, 'WTO TRIPS Agreement and its Implications' (n 33) 8; Cullet P (n 2) 143; ECOSOC (n 4) para 43; Forman L (n 41) 350; Hestermeyer H (n 1) 151.

¹⁷⁰ Abbott FM, 'Trade in Medicines' (n 8) 129.

¹⁷¹ ECOSOC (n 4) para 58.

¹⁷² Forman L (n 41) 352.

¹⁷³ Bernieri RC, 'Intellectual Property Rights in Bilateral Investment Treaties' (n 114) 556; Cullet P (n 2) 144; Sell SK (n 129) 57-58.

protection standards and limitations of flexibilities.¹⁷⁴ It can thus be observed that the current international patent regime is particularly suitable for the pharmaceutical industry in the developed world, with the majority of pharmaceutical patents being held by corporations from OECD countries.¹⁷⁵ This is unsurprising when considering that 75% of the global pharmaceutical sales take place in North America, Europe and Japan alone.¹⁷⁶ The implication of the majority of pharmaceutical patents being held by corporations in industrialised nations, is that such patents not only restrict the affordability of medicines, but further lead to a wealth transfer from the developing world to OECD countries.¹⁷⁷

In developing countries, the importance of affordable medicines is of such impact that the human costs of higher priced patented products do not seem to be justifiable by the marginal increase in research incentives such markets provide.¹⁷⁸ Thus, it seems particularly unfair that the shortcomings in negotiation power of developing countries and LDCs were exploited by industrialised countries to force IP standards upon the developing world which are counter-productive to their development progress.¹⁷⁹ While developing countries gained enhanced access to markets in the global North, it cannot be denied that inappropriately high IP protection nevertheless impairs the process of economic development.¹⁸⁰ Even greater, however, are the social costs inherently connected to pharmaceutical patents in developing countries. While from a trade perspective, it is true that enhanced market access has furthered the interests of developing countries, these benefits come at an extensive trade-off at the expense of public health.¹⁸¹ As will be elaborated in the second section of this chapter, it can be generally observed that the advantages of increased patent protection have commonly been overestimated, while the welfare losses were often misjudged or ignored.¹⁸² Furthermore, it is not conclusively established how far changes to IP protection –

¹⁷⁴ Anderson B, 'Better Access to Medicines: Why Countries are Getting "Tripped" up and Not Ratifying Article 31-Bis' (2010) 1 Case W. Res. J.L. Tech. & Internet 165, 176; Hestermeyer H (n 1) 159; Richards DG (n 32) 268, Trouiller P and others (n 165) 2191.

¹⁷⁵ Abbott FM, 'WTO TRIPS Agreement and its Implications' (n 33) 2 and 4.

¹⁷⁶ Smith RD, Correa C and Oh C (n 19) 684.

¹⁷⁷ Abbott FM, 'WTO TRIPS Agreement and its Implications' (n 33) 4.

¹⁷⁸ Flynn S, Hollis A and Palmedo M (n 14) 191.

¹⁷⁹ Richards DG (n 32) 267.

¹⁸⁰ Abbott FM and Reichman JH (n 156) 925.

¹⁸¹ *ibid*; Dutfield G and Suthersanen U (n 137) 135.

¹⁸² *cf.* Bernieri RC, 'Intellectual Property Rights in Bilateral Investment Treaties' (n 114) 560.

irrespective of the direction – actually affect the future availability of new medicines.¹⁸³

As analysed above in 4.2.1, adequate standards of patent protection can, at least to a certain extent, have positive impacts on the right to health by providing enhanced research incentives.¹⁸⁴ If sufficiently balanced, the patentability of pharmaceuticals may actually be in compliance with the right to health, as according to the UN Economic and Social Council the duty to fulfil under the right to health entails the obligation that states actively promote health related research.¹⁸⁵ A constant increase of IP protection levels, on the other hand, is unlikely to lead to more or faster developments being made in the pharmaceutical sector.¹⁸⁶ Conversely, unreasonably high standards of IP protection may actually hinder future research by restricting access to knowledge, as elaborated below in 4.3.2.4. Furthermore, even where patents actually lead to increased research activity, they cannot be regarded as unconditionally justified, particularly where the protection of economic interests leads to impairments of other areas of the right to health by restricting the affordability of medical products.¹⁸⁷ As the accessibility of medicines is integral to the realisation of the right to health, states are obliged to safeguard the affordability of drugs by ensuring that appropriate prices are maintained.¹⁸⁸ This is further in accordance with the responsibility of states to protect the public against harmful activities of third parties, which requires governments to regulate the scope of action of the private business sector to ensure that commercial exploitation does not impair the enjoyment of the right to health.¹⁸⁹

Additionally, according to the CESCR, entering into international agreements may lead to human rights violations, when such agreements conflict with the prior existing obligations of states under the ICESCR.¹⁹⁰ Thus, an international trade agreement that restricts the capability of states to comply with right to health obligations is

¹⁸³ Abbott FM, 'Trade in Medicines' (n 8) 134; Cullet P (n 2) 142.

¹⁸⁴ Abbott FM, 'Trade in Medicines' (n 8) 135; ECOSOC (n 4) para 29.

¹⁸⁵ ECOSOC (n 4) paras 31 and 59.

¹⁸⁶ Abbott FM, 'Trade in Medicines' (n 8) 135.

¹⁸⁷ ECOSOC (n 4) paras 37 and 42.

¹⁸⁸ Hunt P and others, *Neglected Diseases* (n 51) 30; Hestermeyer H (n 1) 138.

¹⁸⁹ Hunt P and others, *Neglected Diseases* (n 51) 12.

¹⁹⁰ Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights)* (11 August 2000) UN Doc E/C.12/2000/4, paras 39 and 48; Cullet P (n 2) 158.

incompatible with international human rights law.¹⁹¹ In other words, where international IP standards lead to a restriction of the accessibility of medicines, the strict compliance with such standards may be regarded, under right to health considerations, as a ‘deliberately retrogressive step’, which constitutes a direct violation of Article 12 ICESCR.¹⁹² While states thus have a clear duty to ensure that patent rights do not lead to the unaffordability of medicines, the net effect of the international patent regime, as elaborated above in 4.2.2, in fact severely restricts the capability of governments to comply with this human rights obligation.¹⁹³ The legal and political implications of such a potential violation of the ICESCR, however, may be expected to be marginal due to the lack of a sufficiently defined hierarchy between different treaty regimes under international law. This discrepancy can in fact be observed when considering how governments continuously agree to increases of patent protection in TRIPS-Plus FTAs – such as the Trans-Pacific Partnership Agreement (TPP) in recent years – that may lead to adverse impacts on public health.

As has been indicated in chapters 1.3 and 3.2.1.2, health is a basic human need of particular magnitude for realising and safeguarding that all individuals can enjoy a life in dignity. For this reason, I follow the opinion that adherence to the right to health should always be prioritised in situations of norm conflicts.¹⁹⁴ This is not to say, however, that pharmaceutical patents should be abolished all together, but rather that the establishment of an adequate balance ‘with the primary objective of promoting and protecting human rights’ is required.¹⁹⁵ Even where the right to IP is acknowledged as a human right under Article 15 ICESCR, the UN Economic and Social Council has clarified that a balanced approach to IP ‘should not work to the detriment of any of the other rights in the Covenant.’¹⁹⁶

Finally, this section turns to Sub-Question 3.1:

Do the aims and purposes of patents justify a short-term restriction of the accessibility of medicines?

¹⁹¹ Hunt P and others, *Neglected Diseases* (n 51) 37.

¹⁹² CESCR, *General Comment No. 14* (n 190) para 48; Cullet P (n 2) 156, 157 and 160.

¹⁹³ cf. Hunt P and others, *Neglected Diseases* (n 51) 12.

¹⁹⁴ cf. Cullet P (n 2) 160.

¹⁹⁵ ECOSOC (n 4) para 13.

¹⁹⁶ *ibid.*

Here it is recognised that a number of controversies are raised. Generally speaking, it can be held that pharmaceutical patents may be justified to a certain extent if they adequately fulfil their purposes without leading to inappropriate limitations on the accessibility of medicines.¹⁹⁷ The justification can be derived from the fact that adequate levels of patent protection benefit the future availability of new medications by encouraging investments into pharmaceutical R&D.¹⁹⁸ While a short-term restriction of the accessibility of medicines thus may be justified, a controversy arises regarding the question whether the minimum patent period of 20 years under TRIPS can actually be regarded as a short-term restriction, considering that the affordability of medical treatment directly impacts human health and life. Therefore, the justification of the international patent regime depends on the establishment of an adequate balance between the future availability of new medicines and current public health requirements.

Under the initial TRIPS Agreement, it is possible to achieve such a balance, at least in certain circumstances. This, however, depends on how the agreement is implemented into domestic law, and to what extent the use of the flexibilities and exceptions is facilitated. TRIPS-Plus Agreements, on the other hand, frequently aggravate the negative impacts of pharmaceutical patents, by, *inter alia*, limiting the freedom to adequately utilise the flexibilities and exceptions provided by TRIPS and the Doha Declaration without adding any compensating benefits to the public interest. TRIPS-Plus provisions thus thwart the establishment of an adequate balance between private economic interests and the public interest in health, and therefore cannot be deemed as justified. Ultimately, an adequate balance can only be achieved, and any short-term restrictions of the affordability of medicines can only be justified, on the basis that patents in fact entirely fulfil their purposes.¹⁹⁹ While it can be concluded that in theory a short-term restriction of the affordability of medicines may be justified if this considerably enhances the enjoyment of the right to health in the future, the current international patent regime does not seem to be capable of establishing an adequate balance. It can, therefore, be submitted that the potential advantages of pharmaceutical

¹⁹⁷ cf. Dutfield G, 'Healthcare Innovation and Patent Law's' (n 4) 468.

¹⁹⁸ Cullet P (n 2) 157.

¹⁹⁹ cf. Hestermeyer H (n 1) 159.

patentability do not justify the concomitant extensive trade-offs in the area of public health.

4.3 Do Patents on Medical Products Actually fulfil their Purposes and Objectives?

After establishing that in order to be justified, pharmaceutical patent rights need to be adequately balanced with public health interests, it is submitted that any restriction of the affordability of medicines can only be accepted if pharmaceutical patents sufficiently fulfil their purposes and lead to an enhanced availability of new medicines in the future. The following analysis therefore scrutinises whether the provisions of the international patent regime are actually capable of fulfilling the promises made in favour of patent protection, as specified above in 4.2.1. As the negative consequences of pharmaceutical patents especially disadvantage developing countries, the purpose fulfilment of the international patent regime is scrutinised with particular regard to the interrelation between market incentives and poverty levels in developing countries.

4.3.1 Argument 1: The Disclosure Requirement of Patents Enhances Access to Knowledge in the Long-Run

One of the main requirements for the approval of a patent application is that the inventor discloses the technicalities of an invention to the patent office, which will then publish the information in exchange for exclusive marketing rights awarded to the patent holder. While exclusive rights prevent third parties from using this information without the consent of the patent holder, upon the expiry of a patent the knowledge enters the public domain. This is of particular importance, as the public benefits of an invention considerably increase when more people have access to the knowledge that facilitates the utilisation of the invention.²⁰⁰ Without the availability of patents, inventors would potentially be inclined to keep their research results secret. Thus, while pharmaceutical patents provide a short-term restriction on the affordability

²⁰⁰ Bernieri RC, 'Compulsory Licensing and Public Health: TRIPS-Plus Standards in Investment Agreements' (2009) as published on SSRN <<https://ssrn.com/abstract=2101574>> accessed 21 October 2017, 16.

of medicines, in the long-run they enhance the accessibility of such products by directly enabling competing manufacturers to produce generic versions of the drug. This can be illustrated by reference to the example of Coca Cola, as discussed in chapter 2.4.4, which managed to keep its Cola recipe undisclosed as a trade secret, rather than seeking time-limited patent protection, preventing competitors from producing and marketing identical versions of the product for now over 130 years.²⁰¹ If the same strategy was applied by pharmaceutical corporations, the impact on public health would potentially be devastating, as the originator company would be able to maintain a monopolistic position, keeping drug prices high for several decades.

Retaining the technicalities of new pharmaceutical products in secret, however, would not indefinitely prevent the emergence of generic substitutes, as competitors would be free to conduct their own research, and, without patent protection, would be able to replicate the originator drug via reverse engineering. The prices of those drugs would nevertheless remain comparatively high, as each competitor would have to make significant investments into R&D, which would need to be recovered on the markets. Thus, it can be concluded that the disclosure requirement is one of the most significant benefits pharmaceutical patents provide for the public interest.

4.3.2 Argument 2: Patents Enhance Research Incentives into New Medicines

The potentially strongest argument made in favour of patent protection is that by rewarding successful inventors, patent protection aims to create research incentives for the development of new products, including medicines. Upon closer examination, however, it becomes apparent that the current international patent regime does not include sufficient mechanisms to ensure that research is conducted in areas most important for the public interest. As the following analysis shows, patents frequently fail to ensure the creation of adequate incentives for highly required research projects, so that it can be submitted that patents tend to reduce social welfare instead of

²⁰¹ Olafson SE, 'Patents vs. Trade Secrets – Giving Your Business the Competitive Edge' (2007) 4(4) Arizona BioInsider, Special insert
<https://www.lrrc.com/files/Uploads/Documents/Olafson_AZBioInsider.pdf> accessed 22 May 2019.

enhancing the public benefit.²⁰² In other words, the current IP regime provides no guarantee that pharmaceutical patents lead to the development of those medications that are most needed, i.e. drugs for the treatment of conditions that constitute the majority of the global disease burden.²⁰³ As will be elaborated in the following sections, the R&D strategy of pharmaceutical corporations is directed towards the development of products with a high demand in industrialised countries with the intention of recouping investments and turning high profits in wealthy markets.²⁰⁴ As the marginal returns expected from developing country markets are almost minuscule to originator industries, it seems that by focussing on market incentives patents fail to encourage research into diseases that predominantly affect poor populations.²⁰⁵

Furthermore, it is questionable how far patents in developing countries actually enhance the global pharmaceutical research incentive.²⁰⁶ In the majority of cases, a research incentive is established in industrialised nations through the wealthy markets they provide. Commonly, this happens completely irrespective of whether there is a market for the resulting innovative products in the developing world.²⁰⁷ According to Hestermeyer, 80% of pharmaceutical sales are made in the US, the EU, Canada, and Japan, while the entirety of African markets only account for 1.1%.²⁰⁸ It can thus be suggested that the influence of pharmaceutical patents in developing countries and LDCs on the incentive to innovate is insignificant.²⁰⁹ This can be illustrated by reference to the experience with HIV/AIDS drugs in the early 2000s, when public campaigns and particularly the Doha Declaration led to significant reductions of the medicine prices in the developing world. The research-based pharmaceutical industry lost sales to generic manufacturers, and further faced reduced profits due to price cuts, particularly in Brazil and Africa. Nevertheless, the substantial investment into the R&D of new HIV/AIDS treatments continued, because of the expected profits from patients in industrialised countries, where prices remained high.²¹⁰

²⁰² Richards DG (n 32) 268.

²⁰³ Cullet P (n 2) 156-157.

²⁰⁴ cf. Reichman JH (n 10) 257.

²⁰⁵ Cullet P (n 2) 157.

²⁰⁶ Hestermeyer H (n 1) 161.

²⁰⁷ Richards DG (n 32) 273.

²⁰⁸ Hestermeyer H (n 1) 161.

²⁰⁹ *ibid* 162; Richards DG (n 32) 273.

²¹⁰ Richards DG (n 32) 278.

It can thus be observed that pharmaceutical patentability in developing countries only has marginal impacts on the global research incentive, and that market incentives in general are inadequate for promoting research into diseases that mainly affect poor populations.²¹¹ For countries that do not provide valuable markets to the pharmaceutical industry, and therefore only marginally affect the creation of research incentives, a 20-year protection period restricting the accessibility of medicines for the majority of its population, thus seems rather extensive. A study by Scherer therefore concludes with the argument that while the non-patentability of medicines in developing countries would allow them to free-ride on inventions with adverse effects on the welfare of industrialised nations, the overall global welfare would be significantly improved by providing enhanced access to medicines for the poor.²¹²

Additionally, it can be suggested that '[t]he impulse to create and to innovate is intrinsic to human beings.'²¹³ Mankind has been innovative since long before IP rights came into existence. While it may be true that patent rights impact the amount of risk innovators are willing to accept, it can be held that without IP protection innovation would not simply vanish all together.²¹⁴

Although this may be true, the long-standing history of patent rights indicates that the availability of patent protection, at least to a certain extent, furthers inventiveness. This does not substantiate, however, that prolonged patent periods are actually the best method for creating research incentives.²¹⁵ As will be elaborated in the following sub-chapters, the current international patent system does not adequately provide incentives for ground-breaking research, but rather facilitates the patentability of minor inventions.²¹⁶ Pharmaceutical research is mainly driven by prospective profitability, which increases when R&D costs can be kept low and products can be marketed to a large number of customers.²¹⁷ Thus, pharmaceutical research is often directed towards particularly well-selling products, such as life-style drugs, minor improvements of existing products with low-risk research investments, and me-too

²¹¹ cf. Hestermeyer H (n 1) 162.

²¹² Scherer FM, 'A Note on Global Welfare in Pharmaceutical Patenting' (2004) 27 *World Economics* 1127, 1141.

²¹³ Richards DG (n 32) 269.

²¹⁴ cf. *ibid.*

²¹⁵ *ibid* 269-270.

²¹⁶ Dutfield G, 'Healthcare Innovation and Patent Law's' (n 4) 462.

²¹⁷ Hestermeyer H (n 1) 160.

drugs, i.e. chemically amended substances with similar effects as existing blockbuster drugs.²¹⁸

4.3.2.1 Counterargument 1: Neglected Diseases

The fact that pharmaceutical patents fail to provide adequate incentives for the development of urgently required medications can best be observed by analysing the insufficient encouragement provided for the research into neglected diseases which mainly affect the poor. In its broadest interpretation, the term ‘neglected diseases’ can refer to all health conditions for which treatment is not available or accessible for a wide variety of reasons.²¹⁹ In a more conventional sense, neglected diseases specifically refer to conditions with low research activity due to a failure of market incentives. In this sense, neglected diseases commonly affect marginalised and vulnerable groups living in poverty, particularly in rural areas in developing countries.²²⁰ Due to the climate and geographical location where most neglected diseases most commonly appear, they are at times also referred to as tropical diseases.²²¹ While neglected diseases may also affect poor groups within the population of developed countries, they generally do not provide wealthy markets for medicines,²²² so that the research into treatment opportunities is neglected by the industry. Thus, neglected diseases can be identified as a direct consequence of poverty, commonly hitting those who already lack access to health care facilities and services, and whose concerns often remain unaddressed.²²³ Especially for developing countries, neglected diseases constitute a serious burden, not only because they affect the lives of people who are infected or at high risk of infection, but because they also affect a country and its development process due their adverse impact on working capacity, health care costs, and education.²²⁴ According to Hunt, neglected diseases are therefore ‘both a cause and a consequence of human rights violations.’²²⁵

²¹⁸ *ibid.*

²¹⁹ Hunt P and others, *Neglected Diseases* (n 51) 20-21.

²²⁰ *ibid* 1 and 3; Trouiller P and others (n 165) 2188.

²²¹ Hunt P and others, *Neglected Diseases* (n 51) 3.

²²² Infectious and parasitic diseases, for example, constitute one third of the global disease burden, but merely account for 5% of the conditions that affect industrialised nations. See thereto: Trouiller P and others (n 165) 2188.

²²³ Hunt P and others, *Neglected Diseases* (n 51) 4.

²²⁴ cf. *ibid* 3; Trouiller P and others (n 165) 2188.

²²⁵ Hunt P and others, *Neglected Diseases* (n 51) 3.

The difficulty of tackling neglected diseases can be attributed to market failures which are inherent to the functionality of patents in that the augmented private power attributed to the pharmaceutical industry does nothing to encourage addressing the needs of the marginalised and poor.²²⁶ Thus, the R&D of medications for the treatment of neglected diseases remains largely insufficient and underfunded as ordinary market incentives fail to cater for the requirements of destitute markets.²²⁷ Consequently, it can be observed that the incentive created by patents and market forces is insufficient when it is appreciated that ‘only 10% of global funding for research goes towards diseases which affect 90% of the world’s population’.²²⁸ Trouiller et al identified that between 1975 and 1999 only 16 medications were developed and approved for the treatment of tropical diseases and tuberculosis, compared to a total of 1393 drugs that were approved throughout this period.²²⁹ Similarly, of the estimated 2100 drugs in development between 1999 and 2000, only 18 research projects specifically addressed neglected diseases.²³⁰ Additionally, the lower priority allocated to the development of drugs for the treatment of neglected diseases leads to a prolonged average development time of 8.8 years, in comparison to an average of 5.4 years for other medical products.²³¹ Furthermore, a considerably large number of pharmaceutical research projects are abandoned – with, for example, 39% of all drugs in development in the US being prematurely terminated – leading to the emergence of so-called orphan drugs, i.e. chemical compounds that are potentially effective treatment methods, which, however, never make it into clinical trials as the high costs involved are not economically viable.²³² While these medicines are not necessarily intended for the treatment of diseases that predominantly burden developing countries, orphan drug research is likewise neglected because of the low profit margin expected of such products.

²²⁶ *ibid* 38; Hestermeyer H (n 1) 162.

²²⁷ Abbott FM, ‘WTO TRIPS Agreement and its Implications’ (n 33) 2; ECOSOC (n 4) para 38; Hunt P and others, *Neglected Diseases* (n 51) 4; Outtersson K, ‘Disease-Based Limitations on Compulsory Licenses under Articles 31 and 31bis’ in Correa CM (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules: Intellectual Property in the WTO Volume I* (Edward Elgar Publishing 2010) 689; Trouiller P and others (n 165) 2189.

²²⁸ Hunt P and others, *Neglected Diseases* (n 51) 38.

²²⁹ Trouiller P and others (n 165) 2188-2189.

For similar results identified for the period between 1975 and 1997, see: Hestermeyer H (n 1) 162.

²³⁰ Trouiller P and others (n 165) 2189-2190.

²³¹ *ibid* 2190.

²³² *ibid* 2191.

While the neglected research activity is thus a direct result of market failures, the issues of neglected diseases must further be attributed to improper public policies in that governments rely solely on the market incentives created by patents to encourage pharmaceutical research.²³³ As the investments of pharmaceutical corporations are largely profit driven, however, there is a general improbability that market forces can lead to the development of products and medications that predominantly improve the welfare in poor countries, irrespective of the availability of patent protection.²³⁴ According to the pharmaceutical industry, the R&D of medications for the treatment of neglected diseases is too expensive and risky to be viable, particularly in consideration of the marginal returns expected from the marketing of the resulting products.²³⁵ In other words, the reluctance of the industry to invest in the development of drugs for diseases that mainly affect the poor – with investments into research relating to neglected diseases commonly being less than 1% of a corporation’s overall research budget – is directly attributable to the risk that adequate financial compensation for such investments cannot be achieved.²³⁶ By nature, patents are thus incapable of providing incentives for research into medicines for which the markets fail to offer desirable returns due to a lack of spending capacity.²³⁷ Outtersen therefore concludes that ‘diseases are neglected due to the poverty of the afflicted, not the lack of IP rights.’²³⁸

As can be seen, the historical experience clearly indicates that market incentives cannot provide adequate stimulation for addressing health conditions that predominantly affect people living in poverty.²³⁹ Most of the medications for the treatment of tropical diseases available today were developed in the first half of the 20th century in close correlation with the demands of colonial powers.²⁴⁰ With the sudden end of colonialism, however, such research efforts have been increasingly abandoned.²⁴¹ While it is only economically logical for private corporations to prioritise research into diseases that mainly affect wealthy countries, the detrimental

²³³ cf. Hunt P and others, *Neglected Diseases* (n 51) 38.

²³⁴ *ibid*; Richards DG (n 32) 273; Smith RD, Correa C and Oh C (n 19) 686; Hestermeyer H (n 1) 160; ECOSOC (n 4) para 38; Trouiller P and others (n 165) 2193.

²³⁵ Trouiller P and others (n 165) 2188.

²³⁶ *ibid* 2190; Byrne S and others (n 72) 301.

²³⁷ cf. Hestermeyer H (n 1) 163-164.

²³⁸ Outtersen K (n 227) 690.

²³⁹ Lopert R and Gleeson D (n 160) 210; Trouiller P and others (n 165) 2192.

²⁴⁰ Trouiller P and others (n 165) 2188.

²⁴¹ *ibid*.

impact of the pharmaceutical industry continuously shifting its focus away from neglected diseases increases public health problems in the developing world.²⁴² According to the objectives and purposes of the TRIPS Agreement, IP rights shall lead to technology transfers and capacity building, thereby enabling developing countries to conduct their own pharmaceutical research. Most low-income countries, however, continue to be devoid of both the economic and technological means required for addressing the neglected diseases that affect them most.²⁴³

It can thus be concluded that pharmaceutical patent rights cannot provide adequate solutions for addressing global health needs, and particularly the disease burdens that predominantly affect poor countries.²⁴⁴ Especially for neglected diseases, a different approach to incentivising research activity is required, which enables corporations to recoup their research investments and to realise sensible profit margins.²⁴⁵ This can be exemplified by reference to the successful experience in finding a treatment for HIV/AIDS. The development of ARV therapies was largely driven by a strong political devotion of industrialised nations, as well as by the fact that HIV/AIDS similarly affected the population of wealthy countries, thereby providing more profitable markets than most other tropical diseases.²⁴⁶

Additionally, it must be noted that the argument of the pharmaceutical industry that the use of compulsory licenses in developing countries is likely to disincentive pharmaceutical research, may hold true for the specific circumstances surrounding neglected diseases, particularly as there are no other wealthy markets for the industry to recoup their research costs.²⁴⁷ This argument, however, may nevertheless be redundant, as there is currently hardly any private research activity conducted into such diseases which could be discouraged.²⁴⁸

²⁴² *ibid* 2192; ECOSOC (n 4) para 38.

²⁴³ Hunt P and others, *Neglected Diseases* (n 51) 38; Trouiller P and others (n 165) 2191.

²⁴⁴ Trouiller P and others (n 165) 2193.

²⁴⁵ Abbott FM and Reichman JH (n 156) 981.

²⁴⁶ Trouiller P and others (n 165) 2189.

²⁴⁷ Flynn S, Hollis A and Palmedo M (n 14) 192.

²⁴⁸ Reichman JH (n 10) 257.

4.3.2.2 Counterargument 2: *Me-Too Drugs*

Although it may be true that pharmaceutical patentability creates at least certain research incentives in the medical field, it is unlikely that patents can by themselves ensure that pharmaceutical research is mainly directed towards the development of ground-breaking new medications. As the pharmaceutical industry is profit-oriented, research is likely to be directed at products that promise high returns and successful markets. Thus, pharmaceutical research regularly leads to the development of so-called me-too drugs, which consist chemically of substances that are altered just enough to fulfil the novelty requirement for patentability, while having basically the same effects as well established drugs of competitor companies.²⁴⁹ In other words, me-too drugs are patentable ‘inventions’ that frequently fail to offer any new therapeutic benefits.²⁵⁰

The term ‘me-too drugs’ is particularly employed when a considerable number of similar drugs are marketed by competing companies, with the main aim of receiving a share of the profitability of well-selling blockbuster drugs.²⁵¹ According to Trouiller et al, 68.7% of the pharmaceutical products registered between 1975 and 1999 were me-too drugs, or, in other words, only one third of patentable pharmaceutical products provide distinct therapeutic progress.²⁵² It is thus questionable how far patents satisfy the right to health requirement of encouraging the development of novel medicines, and particularly of new treatment methods to tackle future disease burdens.²⁵³

At the same time, it can be acknowledged that a certain focus on the development of me-too drugs is not entirely negative for public health. The availability of equivalently effective substitutes can reduce the prices of patented medicines through a timely introduction of competition, although this price reduction cannot be expected to be on a par with the benefits of introducing generic drugs to the markets.²⁵⁴ On the other hand, excessive investment into the development of profitable me-too drugs entails the risk that research budgets are shifted away from the R&D of other new medications.²⁵⁵ Furthermore, future research efforts may be hindered by the culmination of a large

²⁴⁹ cf. ECOSOC (n 4) para 39.

²⁵⁰ Lopert R and Gleeson D (n 160) 210.

²⁵¹ Henry D and Searles A (n 15) 9.8.

²⁵² Trouiller P and others (n 165) 2189 and 2193.

²⁵³ ECOSOC (n 4) para 39.

²⁵⁴ *ibid*; Hestermeyer H (n 1) 148.

²⁵⁵ Henry D and Searles A (n 15) 9.8.

number of patents on similar chemical substances in the hands of a limited number of corporations.²⁵⁶ It is therefore questionable whether the marginal price reductions offered by patented me-too drugs provide an adequate balance to the concomitant loss of investments in other vital areas of pharmaceutical research.²⁵⁷ Here, similar to the issues of neglected diseases, patent protection offers an incentive for the industry to seek high profitability, but fails to encourage investments into the R&D of the medicines most needed to tackle pressing disease burdens.

4.3.2.3 Counterargument 3: The Relaxation of Patentability Requirements and Successive Patent Periods

So far, it has been argued that patents fail to provide the intended research incentive required for the development of fundamentally novel medicines. Due to inherent market failures, patents are by nature incapable of promoting research into highly required medications for the treatment of diseases that mainly affect the poor. Furthermore, the intense profit orientation of the pharmaceutical industry has led to the relocation of research budgets, now aiming for the development of imitator drugs without any distinct therapeutic advancements. It must therefore be questioned, to what extent the inventions brought about by pharmaceutical research activity actually deserve patent protection? Currently, however, patent laws fail in providing means to identify adequate protection levels and periods for each individual invention.²⁵⁸ This is of particular concern in consideration of the continuous relaxation of patentability requirements, and especially the introduction of the patentability of new uses, in a number of TRIPS-Plus FTAs, as elaborated in chapter 2.5.1.1.

The requirements set out for the patentability of innovations provide the essential parameters according to which an invention arguably deserves the enjoyment of patent protection. Subsequent to the initial TRIPS Agreement, however, those requirements were continuously amended, leading to a progressive reduction of patentability standards in favour of the research-based industry, most notably seen in the relaxation of novelty requirements.²⁵⁹ These changes are controversial, as they do not seem to

²⁵⁶ ECOSOC (n 4) para 39.

²⁵⁷ cf. Henry D and Searles A (n 15) 9.8.

²⁵⁸ cf. Hestermeyer H (n 1) 159.

²⁵⁹ Dutfield G, 'Healthcare Innovation and Patent Law's' (n 4) 458.

follow a sensible purpose or objective enhancing the public benefit.²⁶⁰ Conversely, the relaxation of patentability requirements destabilises the already fragile balance between private and public interests. Not only does this relaxation lead to a larger number of drugs being patented, incurring higher costs for patients in need of treatment, but further, the reduction of novelty requirements is counterproductive to providing real research incentives by facilitating the patentability of minor adjustments of prior known products.

Where the novelty requirement is reduced to a point that new uses of prior known products qualify for patentability, simple changes to recommended dosages, different ways of administering a drug, or minimal changes to the chemical structure of existing drugs can be utilised to extend the monopoly position of originator companies far beyond the initial 20-year patent period.²⁶¹ In particular, the patentability of new dosages is of major concern for public health considerations, as AbbVie, for example, managed to receive a patent on a new dosage that was already known to professionals in the medical field, and thereby known to prior art.²⁶² While a new dosage may actually have clinical benefits for the treatment of certain patients, patents on such new uses prevent doctors from prescribing cheaper generic drugs to be used with a newly patented dosage.²⁶³ In other words, the new dosage can only be administered by prescribing the expensive patented product.

Additionally, it must be noted here that the patentability of new uses of known products arguably can be identified as an infringement of the regulations provided by the TRIPS Agreement. This is because, first and foremost, Article 27(1) TRIPS explicitly requires patentable products and processes to be new, and to involve an inventive step.²⁶⁴ The ‘inventive step’ requirement shall furthermore be synonymous with ‘non-obvious’.²⁶⁵ It is thus questionable whether new uses of known products fulfil these requirements, particularly where different dosages adjusted to the needs of individual patient groups are obvious to health care professionals, i.e. to persons skilled in the arts. Furthermore, Article 27(1) provides that patents shall not

²⁶⁰ *ibid* 453.

²⁶¹ *ibid* 458 and 463; Abbott FM, ‘Trade in Medicines’ (n 8) 120 and 129.

²⁶² Michelsohn A, ‘Drug-Patent Abuse’ (n 10).

²⁶³ *ibid*.

²⁶⁴ TRIPS Agreement (n 37) Article 27(1).

²⁶⁵ *ibid* Footnote 5 to Article 27(1).

discriminate between different fields of technology.²⁶⁶ According to Dutfield, however, TRIPS-Plus patentability standards seem to privilege pharmaceutical products, the only field of technology capable of adequately utilising the patentability of new uses of known substances, with the option of acquiring patents on innovations that fail to satisfy the novelty requirement of the TRIPS Agreement.²⁶⁷ Conversely, in other fields of technology the novelty and non-obviousness requirements appear to be much more strictly applied.²⁶⁸

From a different angle, however, the patentability of new uses in the pharmaceutical sector may prove itself to be a double-edged sword. On the one hand, a number of chemical structures found in medications may actually have beneficial effects for the treatment of a variety of different diseases; other than those for which a drug was originally approved.²⁶⁹ A prime example for such a drug can be seen in Aspirin, which, as elaborated in chapter 2.5.1.1, was initially marketed as a mild pain killer. Since further research into the chemical compounds of Aspirin was conducted, it has been discovered that the drug is also effective for the treatment of heart disease and colorectal cancer. As those research results constitute considerable improvements in the medical field, and as similar advancements may be expected from other chemical compounds, it seems sensible to acknowledge that there are certain benefits attached to the patentability of new uses as incentives for continuous research into existing medicines.²⁷⁰

The downside, on the other hand, is that the patentability of new uses also provides a different incentive for economic disclosure strategies, referred to as ‘patent evergreening’, as elaborated in chapter 2.5.1.1. IP systems that provide more opportunities for the patentability of new uses of known substances make it effectively easier for corporations to receive successive patents.²⁷¹ By utilising evergreening strategies, it becomes advantageous for pharmaceutical corporations to keep certain research results secret when applying for an initial patent, disclosing further treatment opportunities only at a later stage of the life cycle of a drug, in order to extend

²⁶⁶ *ibid* Article 27(1).

²⁶⁷ Dutfield G, ‘Healthcare Innovation and Patent Law’s’ (n 4) 454 and 467.

²⁶⁸ Michelsohn A, ‘To Make Healthcare More Affordable’ (n 45).

²⁶⁹ Dutfield G, ‘Healthcare Innovation and Patent Law’s’ (n 4) 457 and 460.

²⁷⁰ *cf.* *ibid* 468.

²⁷¹ *ibid.*

monopoly positions by receiving successive patents.²⁷² As successive patents receive another full 20-year protection period, it must be questioned whether the patentability of new uses and minor advancements hinders real innovation because the incentive to invest in expensive high-risk research is reduced when the same protection is granted for low risk investments.²⁷³ Thus, the opportunity of ‘gaming’ the patent system diverts research activity away from real innovation, while strategic economic planning is incentivised instead.²⁷⁴ As the patentability of new uses and incremental improvements therefore fails to provide adequate research incentives, a further protection period of 20 years seems imbalanced and unjustifiably long.²⁷⁵

From a public health standpoint, lengthy monopoly periods only seem to be just about justifiable where patents are awarded in order to incentivise and reward true pharmaceutical innovation.²⁷⁶ The development of follow up inventions and new use applications, on the other hand, only require minor inventiveness and there are considerably lower costs and risks involved than in substantially new R&D activities.²⁷⁷ Similarly, the clinical trials required for the market approval of new dosages are significantly less expensive and risky than the clinical trials required for novel medications.²⁷⁸ It is therefore submitted that minor advances with limited therapeutic improvements do not seem to justify the award of a successive full length monopoly positions, keeping drug prices high after the initial patent period expires.²⁷⁹

It must be noted here, however, that at the end of an initial patent period the originally patented product enters the public domain irrespective of the award of a successive patent, as at that point only a new use, a new dosage, or amendments of the chemical structure of a drug are patentable.²⁸⁰ By engaging in excessive marketing campaigns, however, the research-based industry aims to convince patients that minor improvements are of such magnitude that they decide to purchase the expensive newly

²⁷² Stuhldreier M, ‘The Trans-Pacific Partnership Agreement and its Threats to the Affordability of Medical Products in Developing Countries’ (2016) 19 *Trinity C.L. Rev.* 175, 183-185.

²⁷³ Dutfield G, ‘Healthcare Innovation and Patent Law’s’ (n 4) 466.

²⁷⁴ *ibid* 466 and 468.

²⁷⁵ *cf. ibid* 468-469.

²⁷⁶ *cf. Michelsohn A*, ‘To Make Healthcare More Affordable’ (n 45).

²⁷⁷ *cf. Michelsohn A*, ‘Drug-Patent Abuse’ (n 10).

²⁷⁸ *ibid*

²⁷⁹ *ibid*; Michelsohn A, ‘To Make Healthcare More Affordable’ (n 45).

²⁸⁰ Abbott FM, ‘Trade in Medicines’ (n 8) 120 and 129; Michelsohn A, ‘To Make Healthcare More Affordable’ (n 45).

patented version of a drug, rather than a generic copy of the old drug.²⁸¹ Here, the pharmaceutical industry takes advantage of a severe imbalance between the seller and the consumer, generated by the fact that patients are not consumers in the regular sense.²⁸² Patients, as consumers of pharmaceutical products, commonly lack the medical knowledge required for making informed choices about which drug to purchase, and therefore completely rely on assistance provided in form of expert advice.²⁸³ Physicians, however, may be reluctant to prescribe generic drugs where the originator company is awarded a patent on a new use or a new dosage, as prescribing a generic product for patented new uses or dosages may be construed as a patent infringement committed by the doctor.²⁸⁴ In other words, generic pharmaceuticals can only be marketed and utilised for the treatment of certain health conditions, but not for all the conditions a chemical compound can effectively be used to treat.²⁸⁵ Consequently, the award of successive patents continues to limit competition on the markets, leading to higher prices for medicines even where an initial patent period has expired.²⁸⁶

It can therefore be concluded, that even though the patentability of new uses and new dosages may provide a certain incentive for conducting further research into existing medical products with the possibility of improving available treatment methods, the drawbacks of the relaxation of patentability requirements outweigh any advantages. In particular, the patentability of new uses of known substances facilitates strategic economic planning, and the patentability of minor changes to the chemical structures of drugs facilitates the protection of meagre clinical advancements, rather than providing real research incentives. This leads to an unjustified artificial restriction of competition, which in its extremes can take the form of excessive patent evergreening, keeping drug prices high for decades after an initial patent period expires. As the research focus of the pharmaceutical industry may further be shifted away from essential areas addressing major disease burdens, it can be submitted that from a right

²⁸¹ Abbott FM, 'Trade in Medicines' (n 8) 120; Dutfield G, *Intellectual Property Rights and the Life Science Industries* (n 45) 27.

²⁸² Henry D and Searles A (n 15) 9.6.

²⁸³ *ibid* 9.7.

²⁸⁴ Dutfield G, 'Healthcare Innovation and Patent Law's' (n 4) 461-462.

²⁸⁵ *ibid* 462-463.

²⁸⁶ *ibid* 463.

to health perspective the relaxation of patentability requirements is imbalanced and inadequate.

4.3.2.4 Counterargument 4: Patents Create Obstacles Preventing Further Innovation

Thus far, this analysis indicates that the contribution of pharmaceutical patentability to the creation of adequate research incentives is rather limited. The extent to which changes to the level of patent protection – irrespective of the direction – impact future research activity, therefore, remains controversial.²⁸⁷ While an adequate degree of protection may indeed facilitate a certain amount of investments into pharmaceutical R&D, there is no indicator that the continuous strengthening of patent rights positively affects innovation.²⁸⁸ Conversely, as will be shown in this section, excessive patent protection may in fact create obstacles for future research activity.

Innovation is frequently brought about by research activity that builds upon prior discoveries.²⁸⁹ If the patent protection of older inventions is too stringent, researchers are prevented from utilising existing knowledge, whereby future innovation is delayed.²⁹⁰ Thus, the continuous increase of protection levels directly contradicts the very purpose of patents – i.e. the stimulation of innovation – by restricting the innovative progress of competitors.²⁹¹ In other words, when the patents awarded are too broad, they can be used to effectively prevent any further research activity.²⁹² This is of particular concern in the field of pharmaceuticals, as the development of an administrable medicine commonly requires several stages of innovation, each of which could suffice for patentability creating a further obstacle for researchers.²⁹³ Taking into account the possibility of strategic disclosure and patent evergreening, the development of medicines that build upon prior inventions can be severely hindered for unreasonably lengthy periods of time. Restricting the possibility of utilising existing knowledge through the provision of excessive exclusive rights will ultimately

²⁸⁷ cf. Abbott FM, ‘Trade in Medicines’ (n 8) 134.

²⁸⁸ *ibid* 135.

²⁸⁹ *ibid*; Richards DG (n 32) 268.

²⁹⁰ Abbott FM, ‘Trade in Medicines’ (n 8) 135; Richards DG (n 32) 268; Smith RD, Correa C and Oh C (n 19) 689.

²⁹¹ cf. Richards DG (n 32) 268.

²⁹² ECOSOC (n 4) para 40.

²⁹³ *ibid*.

delay technological progress in both developing and industrialised countries.²⁹⁴ According to the UN Economic and Social Council, the provision of excessive patent protection can therefore constitute an undue restriction of medical research, which stands in contrast to Article 15 ICESCR which requires that the protection of private interests is adequately balanced with the public interest of advancing and disseminating medical knowledge.²⁹⁵

Furthermore, patents may hinder pharmaceutical research in another way. This is where the public interest in a specific medication is of such concern to a country that the fear of high prices resulting from patent protection may incline governments of developing countries to keep certain information secret. This was the case in 2007, for example, when the Indonesian government was reluctant to share samples of the H5N1 bird flu virus from Indonesian patients with WHO researchers.²⁹⁶ The reluctance of the Indonesian government stemmed from the fear that pharmaceutical corporations would then gain unrestricted access to those samples, which would have increased the likelihood that the private pharmaceutical industry would develop flu vaccines resulting from this information.²⁹⁷ While the development of treatment methods in itself is positive, the Indonesian government considered the threat that concomitant patent protection would set the prices of bird flu medicines at levels unaffordable for patients living in poverty.²⁹⁸ Thus, Indonesian health officials only accepted to share the samples after the WHO committed to not passing on such samples to private industry without the authorisation of the Indonesian government, in order to protect affordable access.²⁹⁹

Given these points, it can be concluded that the tightening of the international patent regime not only fails to provide adequate research incentives for real innovativeness, but furthermore may in itself create considerable obstacles preventing appropriate continuous research efforts. As a result, an imbalanced increase of patent protection is likely to defeat the very purpose of the international patent regime.

²⁹⁴ Richards DG (n 32) 280.

²⁹⁵ ECOSOC (n 4) para 40.

²⁹⁶ Gelling P, 'Indonesia Defiant on Refusal to Share Bird Flu Samples' *New York Times* (New York, 26 March 2007); Richards DG (n 32) 271.

²⁹⁷ Gelling P (n 296); Richards DG (n 32) 271.

²⁹⁸ Gelling P (n 296); Richards DG (n 32) 271.

²⁹⁹ Gelling P (n 296); Richards DG (n 32) 271.

4.3.2.5 Counterargument 5: High Prices Neither Save Lives Now, Nor in the Future

Lastly, when scrutinising the extent to which patents are capable of providing adequate incentives for promoting pharmaceutical research, it must be considered that one of the main purposes of such incentives is the accessibility of new pharmaceutical products in the future. Pharmaceutical patents thus provide a controversial trade-off, sacrificing the health and life of current populations in order to improve the overall public health environment for the future. Considering the lengthy patent periods awarded under the international IP regime, and the possibility of further extending monopolistic positions on the markets via successive patents on new uses of known products, it is questionable whether patents are actually capable of fulfilling this purpose at all.

In general, it is true that both the health of current populations as well as the health concerns of future populations need to be taken into account.³⁰⁰ When medications, however, are too expensive to be affordable for major sectors of the world's population, advancements in the medical field will only provide meagre benefits for the global health situation.³⁰¹ Thus, when the prices of novel medications are too high, their mere existence is of no value for people in need of treatment who cannot afford those drugs.³⁰² In other words, the value of pharmaceutical innovation is directly dependent on the accessibility and affordability of the resulting pharmaceutical products.³⁰³ It is therefore submitted, that irrespective of the creation of any pharmaceutical research incentives, by inducing high monopoly prices on novel medicines, patents neither save the lives of the poor now, nor in the future.

³⁰⁰ Abbott FM, 'Trade in Medicines' (n 8) 117-118.

³⁰¹ *ibid* 128.

³⁰² *ibid* 134.

³⁰³ 't Hoen E, 'Report of the Commission on Intellectual Property Rights, Innovation and Public Health: A Call to Governments' (2006) 84 Bulletin of the World Health Organisation 421, 421.

4.3.3 Argument 3: Patents Lead to Technology Transfer and Enhance Wealth in Developing Countries

Together with the supposed creation of enhanced research incentives, one of the main objectives of the harmonisation of the international IP system is that increased protection of IP rights shall lead to the dissemination and transfer of technology, increasing wealth and ultimately enhancing the welfare of developing countries. It can then be surmised that the introduction of pharmaceutical patentability would lead to capacity building of the pharmaceutical industry in developing countries. This could theoretically lead to remarkable benefits as developing countries would be enabled to utilise new pharmaceutical capacities to address their most pressing public health needs themselves. Unfortunately, however, there is currently no indicator which suggests that increased IP protection actually leads to the transfer and dissemination of technology. Conversely, as will be elaborated in this section, technology transfers and technological capacity building depend on a wide variety of circumstances, and it seems that stringent IP rights in fact create further obstacles for technological development rather than encouraging the transfer of knowledge to developing countries.

According to Abbott, it is now commonly accepted by researchers in the field of IP and health that the strengthening of patent laws by itself is unlikely to lead to an increase of pharmaceutical research conducted in developing countries.³⁰⁴ This view can be supported by reference to the experiences of several developing countries. A notable example is the situation of Malaysia, which, despite providing suitably strong patent laws, did not attract technology transfers in the pharmaceutical sector.³⁰⁵ Similarly, the strengthening of IP protection levels in Jordan introduced in accordance with the Jordan-US TRIPS-Plus FTA has not led to increases in the pharmaceutical R&D activity of Jordanian corporations.³⁰⁶ The inability of developing countries to attract the anticipated transfer and dissemination of technology thus seems attributable

³⁰⁴ Abbott FM, 'WTO TRIPS Agreement and its Implications' (n 33) 2 and 6.

³⁰⁵ Smith RD, Correa C and Oh C (n 19) 689.

³⁰⁶ Ho CM (n 84) 250.

to factors other than mere IP considerations, including economic short-comings and the lack of an adequate infrastructure in low-income countries.³⁰⁷

It can therefore be seen that a strengthening of IP protection does not automatically increase the pharmaceutical research capacity of developing countries to conduct R&D into medications for diseases that mainly affect the poor, for at least as long as low-income countries continue to struggle with the accumulation of the required economic and technological means.³⁰⁸ Even where certain developing countries, commonly middle-income countries, did manage to develop suitable production capacities in the pharmaceutical sector, local corporations are generally comparatively small and focussed on the production of generic drugs.³⁰⁹ Thus, there remains a distinct gap between the production of replicated chemical structures and the capacity to conduct intensive research into the development of novel medications. It must be further called into question, whether the industry of developing countries that actually manage to develop pharmaceutical research capacity would in fact be incentivised by higher IP standards to conduct research into neglected diseases. With an average annual spending on medicines of \$239 per person in OECD countries, compared to an average spending of less than \$20 in developing countries, and less than \$6 in sub-Saharan Africa, IP rights would nevertheless encourage the pharmaceutical industry of developing countries to invest into the development of drugs that can be marketed in wealthy countries.³¹⁰ It thus seems that even if the strengthening of IP rights led to pharmaceutical capacity building in developing countries, without additional strong political commitments and international cooperation, increased patent protection would be unlikely to notably improve the public health situation for the developing world.

Furthermore, as the majority of pharmaceutical patents is held by corporations from industrialised nations, developing countries are generally required to import expensive patented medications.³¹¹ This means that developing countries have a trade deficit in medical products, and the strengthening of patent rights is highly unlikely to change this situation.³¹² Conversely, the current international IP regime is designed in a way

³⁰⁷ *ibid.*

³⁰⁸ Hunt P and others, *Neglected Diseases* (n 51) 38.

³⁰⁹ Smith RD, Correa C and Oh C (n 19) 685.

³¹⁰ Hestermeyer H (n 1) 163; Trouiller P and others (n 165) 2191.

³¹¹ Smith RD, Correa C and Oh C (n 19) 684-685; Turk M (n 29) 998.

³¹² Smith RD, Correa C and Oh C (n 19) 684.

that facilitates the transfer of wealth from net importers of technology – the majority of which are developing countries – to exporting industrialised nations.³¹³ This may then lead to a further accumulation of the ownership of IP in the hands of the industry in the Global North, to the detriment of the developing world.³¹⁴ Therefore, rather than facilitating the transfer of technology to developing countries, the current international IP system seems to create further obstacles hindering the dissemination of technology.³¹⁵

With this in mind, and in light of the historical experience, it is reasonable to suggest that the international harmonisation of IP standards is unlikely to provide adequate solutions for reducing the wealth gap between the Global North and the Global South.³¹⁶ In particular, appropriate standards of domestic IP protection are clearly dependent on the actual level of a country's development.³¹⁷ Historically, protection standards thus varied widely between different nations, as each country adopted IP laws most suitable to their current economic and technological needs.³¹⁸ The establishment of an international IP regime that strictly requires the same protection levels in both high-income and low-income countries fails to pay due regard to specific individual circumstances and is therefore particularly burdensome for poor countries.³¹⁹ In other words, developing countries are unlikely to benefit from protection standards which are mainly suitable for industrialised nations, as they are commonly designed to further the interests of multinational corporations.³²⁰ Furthermore, the required patentability of inventions in all fields of technology under TRIPS prevents developing WTO member states from implementing economic IP strategies tailored to their specific developmental needs.³²¹ Ultimately, it is thus widely accepted that, at least in the short-term, the negative impacts of strengthened IP laws on developing countries outweigh any benefits thereof.³²²

³¹³ Dutfield G, 'Turning Knowledge into Power: Intellectual Property and the World Trade System' (2005) 59 *Australian Journal of International Affairs* 533, 534; Dutfield G and Suthersanen U (n 137) 134; Hestermeyer H (n 1) 147; Turk M (n 29) 998 and 1004.

³¹⁴ Dutfield G, 'Turning Knowledge into Power' (n 313) 534.

³¹⁵ cf. *ibid* 534-535; Dutfield G and Suthersanen U (n 137) 142.

³¹⁶ Dutfield G and Suthersanen U (n 137) 132.

³¹⁷ Dutfield G, *Intellectual Property Rights and the Life Science Industries* (n 45) 29.

³¹⁸ Dutfield G, 'Turning Knowledge into Power' (n 313) 533.

³¹⁹ *ibid* 534; Dutfield G and Suthersanen U (n 137) 134.

³²⁰ Dutfield G and Suthersanen U (n 137) 132.

³²¹ ECOSOC (n 4) para 24.

³²² Dutfield G, 'Turning Knowledge into Power' (n 313) 534; Dutfield G and Suthersanen U (n 137) 134; Turk M (n 29) 1004.

The historical experience outlines that today's industrialised nations developed their technological capacity at a time when international IP standards were weak, so that local industries were enabled to develop technical know-how by copying and imitating inventions made in other countries.³²³ Correspondingly, it is generally accepted that for human development imitation is a key step towards building the capacity to innovate.³²⁴ Ultimately, today's industrialised countries that benefited from low IP standards quickly moved on from being imitators to advancing their technical capacities and increasing their own innovativeness.³²⁵ For developing countries, and particularly for LDCs, affordable access to technology is therefore regarded as an essential prerequisite to facilitating the development of national industries in order for them to catch up with industrialised nations.³²⁶ By relaxing its patent laws in the 1970s, India, for example, enabled its national pharmaceutical industry to thrive and to establish substantial pharmaceutical R&D capacities.³²⁷ This, however, would not be possible under today's international IP regime. It is thus frequently suggested that via the WTO system, industrialised nations took away the opportunity for developing countries to implement IP laws suitable to their developmental needs, including the utilisation of reverse engineering where required; an opportunity which itself was very integral to the historical industrialisation of the Global North.³²⁸ In other words, under a harmonised international patent regime, developing countries are effectively barred from utilising patents as a tool to facilitate adequate development.³²⁹ Thus, by preventing poorer countries from adopting patent standards appropriate to their specific needs, the harmonisation of international IP laws will ultimately slow down development processes, thereby creating an obstacle for the industrialisation of the Global South and the fight against poverty.³³⁰

While developing countries currently have to endure the IP rules imposed on them by the Western World, according to Dutfield and Suthersanen there is a real likelihood

³²³ Dutfield G, 'Turning Knowledge into Power' (n 313) 544; Dutfield G and Suthersanen U (n 137) 143; Richards DG (n 32) 276.

³²⁴ Dutfield G, 'Turning Knowledge into Power' (n 313) 345; Dutfield G and Suthersanen U (n 137) 142-143.

³²⁵ Dutfield G, 'Does One Size Fit All? The International Patent Regime' (2004) *Harvard International Review* 50, 50.

³²⁶ Richards DG (n 32) 267.

³²⁷ Dutfield G, 'Does One Size Fit All?' (n 325) 51.

³²⁸ Dutfield G, 'Turning Knowledge into Power' (n 313) 545; Dutfield G and Suthersanen U (n 137) 144.

³²⁹ Dutfield G, 'Does One Size Fit All?' (n 325) 53-54.

³³⁰ cf. Richards DG (n 32) 272.

that industrialised nations would change the IP system again if they needed to implement lower IP standards in order to ensure their own keeping up to date with technological developments.³³¹ In fact, early indicators of this strategy may already be observable in the US under the Trump administration. For example, President Trump does not hesitate to pull the US out of international trade agreements, such as the TPP, which he considers unfavourable, irrespective of the considerable advantages such agreements already provide, particularly for the US.³³² *Prima facie*, the revocation of imbalanced TRIPS-Plus FTAs may seem to be a favourable development for access to medicine concerns. Eventually, however, the aim of the Trump administration is to achieve even greater advantages for the US, so that future FTAs may, in fact, lead to even stricter standards favouring US wealth acquisitions at the expense of the poor.

In conclusion, it is submitted that the current international IP regime is designed to protect the interests of the industries of industrialised countries, neglecting the importance of countries being able to utilise appropriate protection levels as a means of technological development. Therefore, it can be observed that the current patent regime is not capable of facilitating the promised technology transfers and capacity building, with the concomitantly expected increase of wealth in developing countries. Ultimately, the mere fact that the WTO regime recognises, and regularly extends transitional periods for the introduction of pharmaceutical patentability in LDCs, as elaborated in chapter 2.4.5, indicates the acknowledgement that the negative effects of unsuitable patent protection outweigh the alleged benefits. In other words, if the advantages provided by pharmaceutical patents would culminate in a net benefit for low-income countries, there would be no need for an extension to the transitional periods.

4.3.4 Argument 4: Patents Increase Foreign Direct Investments (FDI)

In addition to the claim that increases of IP protection would lead to technology transfers and capacity building, it is regularly suggested that higher IP, and particularly

³³¹ Dutfield G and Suthersanen U (n 137) 144.

³³² cf. Taylor A, 'A Timeline of Trump's Complicated Relationship with the TPP' *The Washington Post* (Washington D.C., 13 April 2018).

patent standards, can attract foreign direct investment (FDI) into developing countries. This idea, however, is regarded sceptically and there exists an ongoing controversy surrounding the suggestion that IP protection would automatically increase FDI.³³³ Notably, US corporations hold the view that the FDI undertakings of pharmaceutical corporations are significantly influenced by the strength of local IP standards.³³⁴ In contrast, though, studies conducted on the experiences of Brazil and Turkey indicate that the availability of pharmaceutical patentability did not have any noticeable impacts on FDI levels.³³⁵ This calls into question whether there actually exists a strong relationship between IP rights and FDI decisions.³³⁶ In fact, for several decades, China has managed to receive enormous sums of FDI, irrespective of its comparatively weak IP protection standards.³³⁷ It can thus be suggested that FDI decisions depend on a variety of economic considerations, and that the direct impact of IP rights seems negligible.

Furthermore, in order to provide an actual advantage in the competition for FDI, the IP protection in one country needs to be higher than the protection standards of another country.³³⁸ When all countries have similar IP standards, as anticipated by the harmonisation of the international IP regime under the TRIPS Agreement, then no country will end up having an advantage.³³⁹ The idea that having higher IP standards than the next country brings about advantages in the competition for FDI, then makes TRIPS-Plus Agreements – with all the negative consequences of increasing IP protection – more attractive for developing countries, although there is little evidence that more stringent IP protection actually leads to an increase in FDI.³⁴⁰ Moreover, the aim of attracting FDI may have further adverse impacts on public health because research based pharmaceutical corporations may threaten to reduce their investments into a country as a retaliation against the use of compulsory licenses to address urgent public health needs.³⁴¹ Thus, the wish to receive or maintain FDI may indeed prevent governments from exerting their rights under TRIPS to adequately utilise the

³³³ Dutfield G, 'Turning Knowledge into Power' (n 313) 540.

³³⁴ Dutfield G, 'Does One Size Fit All?' (n 325) 53-54.

³³⁵ *ibid* 53.

³³⁶ Reichman JH (n 10) 256.

³³⁷ *ibid*.

³³⁸ Smith RD, Correa C and Oh C (n 19) 684.

³³⁹ *ibid*.

³⁴⁰ *cf.* Turk M (n 29) 1010.

³⁴¹ Reichman JH (n 10) 256.

exceptions and flexibilities of the agreement for the protection of public health. Ultimately, however, even when a country agrees to higher IP protection standards there is no guarantee that this will actually lead to a commensurable increase of FDI.³⁴²

4.3.5 Concluding Remarks: Patents do not Adequately Fulfil Their Purposes

As can be seen in this analysis, the patentability of pharmaceutical products fails to provide suitable incentives to encourage the risky R&D of radically new medicines, especially for diseases that mainly affect the poor. Thus, the introduction of pharmaceutical patentability in developing countries seems inequitable when the specific health needs of the poor remain neglected.³⁴³ Even where medicines targeting those diseases which predominantly affect people in the developing world enter the markets, such as ARVs for the treatment of HIV/AIDS, patent protection frequently leads to such drugs being priced at an unaffordable level for the majority of the world's population, and therefore negates any benefits for people living in poverty.³⁴⁴ Furthermore, a continuous relaxation of patentability requirements facilitates the patentability of incremental advancements, thereby encouraging strategic economic planning instead of investments into real pharmaceutical R&D activity. It is therefore questionable whether there exists an actual justification for ever-increasing patent protection standards, particularly when considering that patents are not the only system – and potentially not the best way – of encouraging innovativeness.³⁴⁵ Instead, it seems that, especially in the pharmaceutical sector, a different way of incentivising research is required, which pays due regard to both the investments made by the industry as well as the affordability of medicines in developing countries, as further discussed in chapter 5.2.2.5.

Additionally, the harmonisation of patent standards between industrialised nations and the developing world does not provide any considerable benefits for developing countries. In particular, neither the introduction of pharmaceutical patents nor the

³⁴² Smith RD, Correa C and Oh C (n 19) 688.

³⁴³ Cullet P (n 2) 160.

³⁴⁴ *ibid.*

³⁴⁵ Trouiller P and others (n 165) 2193.

harmonisation of IP laws notably impact the FDI decisions of multinational corporations or encourage the dissemination and transfer of technology to developing countries, thereby leading to pharmaceutical capacity building. In effect, due to the general neglect of the interests of developing countries in international IP laws, it is unlikely that poor countries will derive any considerable benefits from the strengthening of patent protection.³⁴⁶ Conversely, this analysis indicates that the stringent harmonisation of IP protection standards between the Global North and the Global South in fact creates obstacles for adequate development processes in low-income countries, by preventing the utilisation of reverse engineering as a means for learning innovativeness.

Ultimately, the preceding analysis leads to a negative answer for Sub-Question 2:

Do patents on medical products actually fulfil their purposes and objectives?

because the introduction of pharmaceutical patentability in developing countries does not lead to the fulfilment of the promises made in favour of patent protection. In particular, the patentability of pharmaceuticals in developing countries does not lead to an enhanced availability of new medicines in the future, especially not of drugs for the treatment of neglected tropical diseases which mainly burden developing countries. It therefore seems reasonable to suggest that a limitation of fundamental human rights cannot be justified by a patent regime which is not capable of fulfilling its purposes.

4.4 Is the Current International Patent Regime Justified?

In the final analysis of this chapter, examining the justification of the current international patent regime, the findings of the previous analyses will be scrutinised to derive an answer to Research Question 3:

Recognising the importance of the right to health and access to medicines for human life in dignity, is the current international patent regime (under TRIPS and TRIPS-Plus) justified when the protection of private interests directly impacts on the affordability of medicines and public health?

³⁴⁶ cf. Lopert R and Gleeson D (n 160) 210.

As stipulated in chapter 3.3, for the purpose of this thesis, human rights that are most essential for a life in dignity are regarded as superior to less fundamental rights. Thus, the right to health is considered superior to property rights, including IP rights. This is in accordance with the very purpose of international human rights law, which stipulates the equal worth of all human beings, and aims to protect the dignity inherent to human existence in itself. Thus, fundamental human rights should always have primacy over trade concerns.³⁴⁷

The issues with patent rights on pharmaceutical products, however, are not simply about conflicting norms between the right to health and IP laws, but furthermore entail a conflict within the right to health itself. On the one hand, the right to health entails the responsibility of states to ensure the affordability of medicines.³⁴⁸ The current international patent regime seems to compromise this human rights objective as the capability of governments to fulfil their duty is directly impaired, inter alia by lengthy patent periods as well as by political pressure directed at restricting the flexibilities provided by the TRIPS Agreement.³⁴⁹ On the other hand, as the provision of essential medicines is a core obligation of the right to health, the inaccessibility and the unavailability of medicines may both constitute a human rights violation.³⁵⁰ This is of particular concern, as the right to health requires the promotion of research for an enhanced availability of new medicines in the future. Patent rights may therefore be in accordance with the right to health when they adequately promote pharmaceutical research activity.

The first thing to remember is that the purpose behind IP rights is the achievement of higher societal objectives, so that patent rights should serve rather than suppress public interests.³⁵¹ Accordingly, patent rights must be identified as a means to an end, and not as an end in themselves.³⁵² In this regard, the British Commission on Intellectual Property Rights suggests that IP rights shall contribute to the fulfilment of economic and social human rights.³⁵³ This, however, does not directly follow from patent laws,

³⁴⁷ cf. Helfer LR (n 100) 49.

³⁴⁸ Forman L (n 41) 353.

³⁴⁹ *ibid*; Helfer LR (n 100) 50-51.

³⁵⁰ Hunt P and others, *Neglected Diseases* (n 51) 33.

³⁵¹ Haugen HM, 'Human Rights and TRIPS Exclusion and Exception Provisions' (2009) 11 JWIP 345, 360; Sell SK (n 129) 58.

³⁵² cf. Sell SK (n 129) 69.

³⁵³ Haugen HM (n 351) 360.

as the international patent regime fails to provide an explicit recognition of human rights concerns.³⁵⁴ In examining this, the first part of this chapter established that the current international patent regime is not adequately balanced, as while the rights of patent holders are clearly defined, there is a general lack of reference to the responsibilities of patent holders towards society.

To now identify if the current international patent regime is justified, it is essential to consider Sub-Question 3.1 on whether the aims and purposes of patents justify a short-term restriction of the accessibility of medicines. As provided here, the right to health entails both the requirement that medicines are affordable as well as that new medicines are available in the future. While under certain conditions a limitation of human rights standards may be justified according to Article 4 ICESCR, the Limburg principles suggest that limitations which directly impact on the life and survival of individuals are never permissible.³⁵⁵ Similarly, the ICCPR, which regulates the right to life, does not contain this type of a general limitation provision.³⁵⁶ Thus, there seems to be a strong case to be made against any restriction on the accessibility of medicines. On the other hand, however, both the affordability of medicines as well as the availability of new drugs are integral requirements of the accessibility of medicines and health care, and may directly impact the life and survival of individuals. It is therefore currently impossible to provide an uncontentious or conclusive answer to Sub-Question 3.1. Sub-chapter 4.2.4 concluded, however, with the suggestion that for a short-term restriction of the accessibility of medicines resulting from patent protection to be justifiable at all, the current international patent regime needs to adequately fulfil its purposes and objectives, thereby promoting pharmaceutical research activity which leads to an enhanced availability of new medicines in the future.

Conversely, however, following an examination of the current international patent regime addressing Sub-Question 3.2, sub-chapter 4.3.5 concluded that patent rights currently do not adequately fulfil their purposes and objectives. Instead of promoting real research activity, the current patent regime rather seems to incentivise incremental innovations and strategic economic planning by which private rights holders can

³⁵⁴ *ibid* 361.

³⁵⁵ Hestermeyer H (n 1) 152.

³⁵⁶ *ibid*.

extend monopoly positions without the requirement of making risky investments into radically new pharmaceutical R&D projects. Furthermore, patent rights completely fail to cater for the needs of poor populations, as medications for diseases that mainly affect the poor offer no profitable markets and therefore do not generate the required market incentives for investments by the profit driven industry.

It can therefore be derived that impairments to the accessibility of medicines resulting from the protection of private rights under the current international patent regime are not justified. While the objectives and purposes of pharmaceutical patentability would potentially have positive impacts on the right to health if adequately fulfilled, the fact that current patent rights are not capable of fulfilling these aims suggests that the imbalances of the international patent regime create obstructions of the right to health without providing any considerable benefits for the public interest. Thus, from a human rights point of view, particularly with regard to the importance of the right to health and access to medicines for a human life in dignity, the patentability of medical products under the current international patent regime is not appropriate. Furthermore, it seems that the current international IP regime is not justified within itself, as at least for the patentability of medical products it becomes apparent that the current rules are not sufficiently capable of fulfilling their very own purposes.

The incapability of patent rights to effectively promote the most needed pharmaceutical research projects is inherently connected to their reliance on commercial market incentives. Hence, it is important to realise that insufficiently regulated medicines markets lack the capability of adequately fulfilling public health requirements.³⁵⁷ As the accessibility of drugs, however, can directly impact the life and survival of patients in need of treatment, it must be acknowledged that the medicines market is more than an economic sales channel for trading consumer goods.³⁵⁸ For this reason, the common argument of market economists suggesting that trade markets should remain free from political interventions but regulate themselves is deficient, as it has become apparent that the pharmaceutical sector suffers from a wide array of market failures.³⁵⁹ Ultimately, pharmaceutical patents themselves are a means for addressing such a market failure; i.e. the failure of a completely competitive

³⁵⁷ Henry D and Searles A (n 15) 9.17.

³⁵⁸ *ibid.*

³⁵⁹ *ibid.*

market, which by itself is not capable of creating adequate incentives for conducting high risk pharmaceutical R&D. The current international patent regime, however, is insufficiently equipped to remedy this failure as it only regulates the private rights of patent holders and not their responsibilities towards society. Lacking an adequate balance between the private and public interests that are involved, and by granting monopolistic powers to rights holders, the current international patent regime leads to an exacerbation of a particular failure of the medicines market; namely the inadequate accessibility of drugs due to profit driven pricing strategies.

With this in mind, it becomes apparent that the provision of private IP rights requires the introduction of counterbalancing mechanisms which ensure both the creation of pharmaceutical R&D incentives while at the same time safeguarding the affordability of medicines by preventing restrictive drug prices.³⁶⁰ For establishing a balance between the right to health and patents rights it is crucial to pay due regard to the social dimension of IP.³⁶¹ According to former UN Special Rapporteur on the Right to Health, Paul Hunt, patents can be described as a ‘social contract’³⁶² by which the research efforts of a patent holder are rewarded with exclusive marketing rights. Once life-saving medicines are developed, a patent holder then ‘has a human rights responsibility to take all reasonable steps to make the medicine as accessible as possible, as soon as possible, to all those in need.’³⁶³ In this regard, it must be reemphasised that the objectives of the TRIPS Agreement explicitly recognise the need to establish a balance between the rights and obligations of IP rights holders ‘to the mutual advantage of producers and users of technological knowledge’.³⁶⁴ While the TRIPS Agreement comprehensively defines the rights of patent holders, there is little clarification of the scope of the responsibilities of rights holders in international patent provisions.³⁶⁵ Furthermore, the TRIPS Agreement only provides minimum protection standards, conferring on states the complete freedom to determine higher levels of protection. As a result, the current lack of clearly defined corporate responsibilities and ceilings of protection, in combination with the push for ever increasing patent

³⁶⁰ cf. Cullet P (n 2) 159.

³⁶¹ *ibid.*

³⁶² Hunt P, ‘Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of health – Annex: Mission to GlaxoSmithKline’ (5 May 2009) United Nations General Assembly, UN Doc A/HRC/11/12/Add.2, para 36.

³⁶³ *ibid* para 37.

³⁶⁴ TRIPS Agreement (n 37) Article 7.

³⁶⁵ cf. ECOSOC (n 4) para 23.

standards under TRIPS-Plus FTAs, generate a substantial obstacle for the establishment of the required balance.

In summary, it can be concluded that the current international patent regime is not justified, and that particularly the restriction of the accessibility of essential medicines cannot be vindicated by the marginal incentive pharmaceutical patents provide for the development of new medications. From an ethical point of view, and in special consideration of human rights and human dignity, it can never be acceptable that human lives are sacrificed for the mere economic purpose of maximising monetary profits. While the current international patent regime may be sufficient for industrialised nations with wealthy markets and social insurance systems, it completely fails to cater for the specific requirements of developing countries and LDCs.³⁶⁶ When reflecting on the historic objectives and purposes of patents, however, it can be observed that the foundational idea behind their protection, namely the fostering of innovativeness for the benefit of the public interest, is generally a sensible approach to enhancing the well-being of human populations. It is therefore suggested that even though the international patent regime is currently not justified, it should not be abolished all together.³⁶⁷ Instead it is submitted that the international IP regime requires substantive revisions and amendments in order to facilitate the establishment of an adequate balance that provides adequate incentives encouraging truly needed pharmaceutical research projects while at the same time ensuring the affordability of medicines for everyone.³⁶⁸

4.5 Concluding Remarks

Based on the premise that for the purpose of this thesis the protection of human health is considered of higher importance than the economic interests protected by private patent rights under international trade law, the present chapter analysed the justification of the international patent regime, inter alia, against the human right to health. In this consideration, it was reemphasised that the right to health entails both the affordability of medicines now, as well as the availability of new medicines in the

³⁶⁶ Outtersson K (n 227) 697.

³⁶⁷ cf. Gumbel M (n 125) 182.

³⁶⁸ cf. Dutfield G, 'Healthcare Innovation and Patent Law's' (n 4) 469; Cullet P (n 2) 155.

future. To identify the justification of the international patent regime, this chapter therefore scrutinised whether the anticipated benefits of newly developed medicines in the future can justify a short-term restriction of the affordability of medicines now. This question, however, cannot be conclusively answered because of ethical intricacies which would require the determination of whether the lives of current patients, or the lives of future patients are of higher importance, which conflicts with the basic human rights principle that all human beings are equal. Ultimately, it was submitted in the first part of this chapter that for such a restriction to be justifiable at all, the international patent regime would need to adequately fulfil all of its objectives and purposes, and ultimately lead to better medical treatment in the future. Scrutinising the objectives and purposes of the international patent regime and the real impacts of pharmaceutical patent rights on both the affordability of medicines and the availability of new medicines in the future, the second part of this chapter analysed whether pharmaceutical patents actually fulfil their aims. After careful examination, it was established that because of an inherent shortcoming – namely that the fulfilment of a public function is simply subjected to market incentives – patent rights are by nature incapable of fulfilling their own purposes. Thus, by restricting the accessibility of medicines, pharmaceutical patent rights are not only unjustifiable from a right to health perspective, but by not adequately fulfilling the objectives and purposes of the international patent regime, cannot be regarded as justified in themselves either. In particular, it was identified that the granting of private exclusive rights requires a counterbalance in form of distinct obligations to ensure that patents fulfil their purposes and not merely hamper the fulfilment of public objectives. Lacking these balancing mechanisms, it is concluded that the current international patent regime cannot be regarded as justified.

Accordingly, it is essential for improving the justness of the international patent regime that the obligations of patentees, particularly of the multinational pharmaceutical industry, are clearly defined, and that some form of benchmarks are introduced which set specific requirements for the patentability of medications, paying due regard to the social dimension of IP. Furthermore, it is crucial that upper limits of patent protection are introduced and explicitly recognised by international IP laws to prevent an unrestricted proliferation of the protection of exclusive private rights to the detriment

of the public interest.³⁶⁹ The following chapter elaborates potential possibilities by which the international patent regime can be improved, indicating that a variety of existing voluntary measures have particular shortcomings in that their effectiveness is completely dependent on the willingness of the for-profit industry to place social aims above their monetary interests. An effective approach therefore requires the introduction of binding rules via amendments to the very IP treaties themselves, beginning with the TRIPS Agreement.

³⁶⁹ cf. Frankel S (n 37) 1030; Xiong P (n 93) 186.

Chapter Five

5 Identifying Responsibilities of the Pharmaceutical Industry

As established by the preceding chapter, the current international patent regime cannot be regarded as justified, either within itself, or with regard to human rights, and particularly the right to health. Notably, the regime fails to sufficiently balance private and public interests, which can be attributed to an inadequate balance of the rights and obligations provided by international patent laws. In particular, it can be observed that while the TRIPS Agreement and TRIPS-Plus agreements provide detailed rights to patent holders, the international patent regime refrains from implementing distinct responsibilities or obligations of rights holders. If anything, the objectives and purposes of Articles 7 and 8 TRIPS imply the general existence of rights holders' obligations, but those obligations are not further defined and commonly neglected. To address this issue, this chapter analyses the possibility of identifying and adopting clear responsibilities of private corporations, and particularly of pharmaceutical patent holders, towards the realisation of the right to health, to ensure that private and public interests are appropriately balanced with each other.

The first part of this chapter elaborates on soft law instruments and voluntary measures, which base the identification of the human rights responsibilities of private corporations on the concept of corporate social responsibility (CSR). This section then aims to provide an answer to Research Question 4:

Why is the corporate social responsibility approach of identifying the human rights responsibilities of the private business sector in non-binding international soft law instruments, insufficient for adequately regulating the pharmaceutical industry's conduct towards the right to health?

The second part of this chapter scrutinises a different approach to establishing a balance between private and public interests, considering the introduction of direct obligations of patent holders by amending the TRIPS patent regime itself. Ultimately, this section aims to answer Research Question 5:

Can responsibilities of pharmaceutical patent holders towards the realisation of the right to health be implemented into the TRIPS Agreement in order to establish a balance between private interests and public health, thereby enhancing the justification of the international patent regime?

5.1 Conventional Ways of Addressing the Human Rights Responsibilities of the Private Business Sector

5.1.1 Introduction to the Identification of Corporate Human Rights Responsibilities

The following section provides an overview of conventional measures taken by the international community, and in particular by the UN, to further the cause of human rights protection, including measures to safeguard the right to health, by providing guidance on the responsibilities of the private business sector and multinational corporations. As will be discussed, these measures generally constitute soft law instruments located in the broad field of corporate social responsibility (CSR), rather than providing binding legal obligations for which non-state actors can directly be held liable. While it is generally welcomed that international organisations provide guidance on the identification of corporate responsibilities towards human rights, the main problem with soft law instruments is that they are voluntary in nature. Therefore, unless domestic governments implement binding legal provisions, corporations have ample leeway to circumvent adherence to responsibilities that conflict with or do not complement their economic interests.

Throughout the processes of globalisation, an international trend has emerged recognising the importance of conducting human actions in a sustainable manner. It is

therefore now widely accepted that the responsibilities of the private business sector exceed the mere goal of profit maximisation, and further entail a social dimension recognised as CSR.¹ Often, however, the main reason for companies to consider their social responsibilities derives from self-interests, as adhering to such responsibilities can enhance the public view of their brand names.² Furthermore, when companies voluntarily take steps towards adhering to CSR, governments might see less necessity for taking legislative measures to regulate corporate activities, so that corporations can maintain a greater degree of independence.³ Nevertheless, it has to be recognised that certain moral responsibilities apply to businesses regardless of their self-interests. As corporate activities can cause social problems, it is the responsibility of businesses to mitigate the consequences of such problems.⁴

According to the Financial Times Lexicon:

CSR is a concept with many definitions and practices. The way it is understood and implemented differs greatly for each company and country. Moreover, CSR is a very broad concept that addresses many and various topics such as human rights, corporate governance, health and safety, environmental effects, working conditions and contribution to economic development. Whatever the definition is, the purpose of CSR is to drive change towards sustainability.⁵

While providing a detailed analysis of CSR, relevant laws and policies, as well as compliance mechanisms, exceeds the scope of this thesis, it is submitted here that while a variety of factors and nuances impact the legal standing of such responsibilities, in summary CSR can be identified as a quasi-voluntary measure of good practice rather than a codex of binding obligations.⁶

Nevertheless, it can be generally observed that the concept of CSR has considerable impact on the ways we understand business and the ways corporations address all stakeholders concerned. In the context of pharmaceuticals and the right to health,

¹ Crane A and Matten D, *Business Ethics* (3rd edn, OUP 2010) 51.

² *ibid* 51.

³ *ibid* 51.

⁴ *ibid* 52.

⁵ Financial Times, 'Financial Times Lexicon: Definition of Corporate Social Responsibility (CSR)' <[http://lexicon.ft.com/Term?term=corporate-social-responsibility--\(CSR\)](http://lexicon.ft.com/Term?term=corporate-social-responsibility--(CSR))> accessed 09 February 2019.

⁶ Principal People, 'What is Corporate Social Responsibility' <<https://www.principalpeople.co.uk/blog/2015/11/what-is-corporate-social-responsibility>> accessed 09 February 2019.

particularly Johnson & Johnson, GlaxoSmithKline (GSK), and Novartis can be identified as prime examples of corporations paying due regard to CSR in their conduct of business. First introduced in 1943,⁷ Johnson & Johnson follows a Credo that identifies the company's first responsibility as being 'to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services.'⁸ Additionally, the Credo explicitly recognises the importance of 'maintaining reasonable prices' as well as helping 'people be healthier by supporting better access and care in more places around the world.'⁹ Similarly, GSK adopts a pricing policy that aims to '[i]mprove the health of millions of people each year by making our products available at responsible prices that are sustainable for our business'.¹⁰ In this regard, GSK's code of conduct commits 'to ensuring access to medicines and patient safety, and to sharing scientific information to help further research and development, wherever possible.'¹¹ Likewise, Novartis adopts an access policy which takes account of income levels and economic realities in pricing strategies, to enhance the affordability of medicines for the poor.¹² Furthermore, the company commits to conducting research into neglected diseases, to which end it established and maintains the specialised Novartis Institute for Tropical Diseases.¹³ Such substantial efforts towards sustainable CSR, however, are not adopted by all actors across the pharmaceutical sector, and may in fact constitute a minority within the industry. Furthermore, while the commitment towards CSR is laudable, the exact scope of specific responsibilities and commitments is left undefined.

With this in mind, international organisations adopted policies and recommendations, aiming to identify the human rights responsibilities of the private business sector by

⁷ Johnson & Johnson, 'Our Heritage: 8 Fun Facts About Our Credo – Johnson & Johnson's Mission Statement' <<https://www.jnj.com/our-heritage/8-fun-facts-about-the-johnson-johnson-credo>> accessed 09 February 2019.

⁸ Johnson & Johnson, 'Our Credo' <<https://www.jnj.com/credo/>> accessed 09 February 2019.

⁹ *ibid.*

¹⁰ GlaxoSmithKline, 'Our Approach to Responsible Business' <https://www.gsk.com/media/5097/our-approach-to-responsible-business_sept-18.pdf> accessed 09 February 2019.

¹¹ GlaxoSmithKline, 'Living Our Values and Expectations: Our Code of Conduct' <<https://www.gsk.com/media/4800/english-code-of-conduct.pdf>> accessed 09 February 2019, 22.

¹² Novartis, 'Affordability' <<https://www.novartis.com/our-company/corporate-responsibility/expanding-access-healthcare/access-principles/affordability>> accessed 16 March 2019.

¹³ Novartis, 'Research & Development' <<https://www.novartis.com/our-company/corporate-responsibility/expanding-access-healthcare/access-principles/research-development>> accessed 16 March 2019.

connecting their strategies to the general concept of CSR. The following sections will discuss two different approaches taken by the international community to address human rights challenges in our changing global economic and ecological reality. The first approach, briefly addressed in sub-chapter 5.1.2, discusses two distinct plans of action drafted by the international community, consisting of (1) the Millennium Development Goals (MDGs), and (2) the successively adopted Sustainable Development Goals (SDGs). While these plans are mainly focussed on the actions of governments and states, they also recognise the importance of including the private business sector for achieving the intended goals. The second approach, discussed in sub-chapter 5.1.3, elaborates soft law guiding principles and guidelines endorsed by the UN, identifying direct human rights responsibilities of the private business sector. This section specifically addresses John Ruggie's 'UN Guiding Principles on Business and Human Rights' focussing on the responsibilities of multinational corporations in general, and Paul Hunt's 'Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines' elaborating the particular responsibilities of the pharmaceutical industry with regard to the right to health.

5.1.2 International Development Goals

After a decade of talks and negotiations, in its 8th plenary meeting on 8 September 2000, the UN General Assembly adopted the 'United Nations Millennium Declaration' including the Millennium Development Goals (MDGs).¹⁴ The MDGs consisted of eight elaborate goals, and several targets which aimed to foster development and lead to a substantial reduction of global extreme poverty levels by the year 2015.¹⁵ For the scope of this thesis, and in connection with the responsibilities of pharmaceutical corporations towards the right to health, Target 8.E of MDG 8 is of particular importance, stating: 'In cooperation with pharmaceutical companies, provide access

¹⁴ UNDP, 'Millennium Development Goals'
<http://www.undp.org/content/undp/en/home/sdgoverview/mdg_goals.html> accessed 09 February 2019.

¹⁵ *ibid.*

to affordable essential drugs in developing countries'.¹⁶ With the assertion of this target, the international community explicitly recognised the crucial importance of involving pharmaceutical corporations in the attempts and ambitions aimed at finding adequate strategies for enhancing the accessibility and affordability of medicines. While not imposing any direct duties or responsibilities on the pharmaceutical industry, the MDGs constituted an important step towards identifying the role of the private business sector for the promotion and protection of the right to health.

According to the United Nations Development Programme (UNDP), the MDGs were a great overall success in that the final Millennium Development Goals Report of 2015 indicates that the MDGs have 'produced the most successful anti-poverty movement in history'.¹⁷ Nevertheless, as can be observed today, the MDGs did not succeed entirely as gross inequalities and extreme poverty continue to burden a majority of developing countries and LDCs; or, as the UNDP puts it, 'the job is unfinished for millions of people'.¹⁸ It is here that the Sustainable Development Goals (SDGs) connect to the MDGs by recognising 'rising inequalities within and among countries' and suggesting that billions of human beings 'continue to live in poverty and are denied a life of dignity'.¹⁹ For this reason, '[t]he new Agenda builds on the Millennium Development Goals and seeks to complete what they did not achieve, particularly in reaching the most vulnerable'.²⁰

Building upon the achievements of the MDGs, the SDGs were adopted by the UN General Assembly Resolution 70/1 on 25 September 2015, taking over where the mandate of the MDGs terminated.²¹ In their scope and ambitions, the newly adopted SDGs go further than the MDGs by providing 17 main Goals with a substantial number of Sub-Targets for each of those goals. This unprecedented approach is particularly ambitious but appears surprisingly successful, at least on paper, supported by and thus

¹⁶ United Nations, 'Goal 8: Develop a Global Partnership for Development' <<http://www.un.org/millenniumgoals/global.shtml>> accessed 20 May 2019; United Nations, 'List of Millennium Development Goals, and Goal 8 Targets and Indicators' <https://www.un.org/en/development/desa/policy/mdg_gap/mdg8_targets.pdf> accessed 20 May 2019.

¹⁷ United Nations, *The Millennium Development Goals Report 2015* (United Nations 2015) 3.

¹⁸ UNDP (n 14).

¹⁹ United Nations General Assembly (UNGA), 'Transforming our world: the 2030 Agenda for Sustainable Development' (21 October 2015) UN Doc A/RES/70/1, para 14.

²⁰ *ibid* para 16.

²¹ *ibid* paras 1 and 3.

applicable to all countries alike.²² The overarching theme provided by the agenda aims to ensure that the needs of every human being are met,²³ in particular by promoting ‘universal respect for human rights and human dignity’.²⁴

Correspondingly, the SDGs reaffirm the importance of the accessibility of quality health care for everyone with the explicit qualification that ‘[n]o one must be left behind.’²⁵ In this regard, the agenda promulgates the intention of paying increased attention to addressing neglected diseases that mainly burden developing countries.²⁶ Furthermore, governments are urged to abstain from adopting unilateral measures imposing sanctions on other states that result in the creation of obstacles for the development process of developing countries.²⁷ Thereby, the SDGs appear to reemphasise that governments should, inter alia, refrain from pressuring developing countries into limiting the TRIPS flexibilities, or into accepting TRIPS-Plus patent standards that are inappropriate for their specific developmental needs.

With reference to the discrepancies between international patent rights and the right to health, Goal 3 of the SDGs is of particular relevance in that it aims to ‘[e]nsure healthy lives and promote well-being for all at all ages’.²⁸ In this regard, Target 3 of Goal 3 strives for the eradication of a number of communicable diseases, including AIDS, tuberculosis, malaria, and other neglected diseases, by 2030.²⁹ To achieve this ambitious aim, Target 8 of Goal 3 elaborates on the accessibility of essential medicines by recognising the importance of their affordability.³⁰ Similarly, Goal 3.b not only acknowledges the importance of the research and development (R&D) of new medicines but furthermore acknowledges the crucial importance of the Doha Declaration reaffirming ‘the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all’.³¹

²² *ibid* para 5.

²³ *ibid* para 4.

²⁴ *ibid* para 8.

²⁵ *ibid* para 26.

²⁶ *ibid* para 26.

²⁷ *ibid* para 29.

²⁸ *ibid* Goal 3.

²⁹ *ibid* Goal 3.3.

³⁰ *ibid* Goal 3.8.

³¹ *ibid* Goal 3.b.

Additionally, Goal 9 of the SDGs aims at the promotion of inclusive and sustainable industrialisation and the fostering of innovation.³² The targets of this goal include the enhancement of technological capacities, particularly in developing countries, by supporting local technological development as well as by increasing the accessibility of information.³³ Furthermore, Goal 10 of the SDGs strives for the reduction of inequalities both ‘within and among countries’.³⁴ In this regard, Target 6 of Goal 10 emphasises the importance of paying due regard to the concerns of developing countries in international negotiations, and Goal 10.a of the SDGs expresses the need to grant differential treatment to developing countries and LDCs.³⁵ When read in conjunction with each other, and applied to the context of this thesis, it can be derived from Goals 9 and 10, that patent rights need to be adequate for the specific developmental needs of developing countries and LDCs, and that further they should not create obstacles for the dissemination and transfer of technologies to, and technological capacity building in, developing countries and LDCs. However, Goal 10.a qualifies this suggestion by stipulating that differential treatment shall be ‘in accordance with World Trade Organisation agreements’.³⁶ It is therefore submitted that the SDGs implicitly require a necessary amendment to the TRIPS Agreement which ensures that patent rights fulfil their objectives and purposes, furthering the cause of the SDGs rather than constituting a potential obstacle for their effective achievement.

With the intention of tackling the most pressing challenges of global sustainable development, it can be observed that many of the targets of the SDGs are extremely ambitious; in fact, some targets may almost be considered unrealistically high. On the other hand, the SDGs set out an agenda of issues that urgently require comprehensive solutions, so that the definition of ambitious benchmarks is conducive for realising the highest possible achievements. While this agenda is mainly applicable to states and governments, highlighting the importance of realising their collective ambitions by revitalising a ‘global partnership for sustainable development’,³⁷ the SDGs furthermore ‘call on all businesses to apply their creativity and innovation to solving

³² *ibid* Goal 9.

³³ *ibid* Goal 9.5, Goal 9.b, and Goal 9.c.

³⁴ *ibid* Goal 10.

³⁵ *ibid* Goal 10.6 and Goal 10.a.

³⁶ *ibid* Goal 10.a.

³⁷ *ibid* paras 61-62.

sustainable development challenges.’³⁸ This call by itself, however, does not impose any binding responsibilities on private corporations and thus simply provides another international declaration suggesting that the private business sector should voluntarily contribute to its implementation. More generally speaking, while setting out clearly defined and qualified goals and targets of what to achieve, the SDGs do not provide any guidance or plans on how those goals and targets shall be achieved in the anticipated timeframe. Thus, specific strategies for the achievement of the SDGs need to be developed and implemented in both national policies and further international instruments. In respect of human rights, and particularly the right to health in line with Goal 3 of the SDGs, the following section elaborates on two international instruments aimed at clarifying the responsibilities of the private business sector towards human rights.

5.1.3 UN Human Rights Guidelines and Guiding Principles

The following section provides an overview of the approach taken by the UN in identifying the international human rights responsibilities of privately-owned corporations. In this respect, the analysis focuses in particular on the UN Guiding Principles on Business and Human Rights, elaborating the human rights responsibilities of corporations in general, and the Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines, identifying in particular the specific human rights responsibilities of the pharmaceutical industry. This thesis is not intended to provide a comprehensive analysis of the scope and content of the specific guidelines and principles of either of the instruments, but rather briefly elaborates on the general structure, scope, and purposes of the frameworks in order to identify their potential shortcomings. For a comprehensive analysis of the UN Guiding Principles on Business and Human Rights see Barakat (2016), Jägers (2011),

³⁸ *ibid* para 67.

Lagoutte (2016), and Wettstein (2015).³⁹ For the Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines see Hunt (2008), Lee and Hunt (2012), and Moon (2013).⁴⁰ This section concludes by submitting that voluntary measures are not strong enough to ensure that corporations adhere to the identified human rights responsibilities, particularly when monetary interests are at stake.

5.1.3.1 John Ruggie's UN Guiding Principles on Business and Human Rights

After a six-year drafting and consultation process conducted by Professor John Ruggie, under his mandate as the UN Secretary General's Special Representative on Business and Human Rights, the UN Guiding Principles on Business and Human Rights (Guiding Principles) were unanimously endorsed by the UN Human Rights Council (HRC) in Resolution 17/4 of 16 June 2011.⁴¹ Thereby, Ruggie introduced a global soft law instrument that explicitly addresses the human rights responsibilities of both states and corporations, establishing authoritative principles that bring together prior regulations and interpretations of the responsibilities of the business sector in a single framework.⁴² The Guiding Principles affirm '[t]he role of business enterprises as specialized organs of society performing specialized functions, required to comply with all applicable laws and to respect human rights'.⁴³ In this regard, the SDGs

³⁹ Barakat N, 'The U.N. Guiding Principles: Beyond Soft Law' (2016) 12 Hastings Bus. L.J. 591; Jägers N, 'UN Guiding Principles on Business and Human Rights: Making Headway towards Real Corporate Accountability' (2011) 29 Neth. Q. Hum. Rts. 159; Lagoutte S, 'The UN Guiding Principles on Business and Human Rights: A Confusing "Smart Mix" of Soft and Hard International Human Rights Law' in Lagoutte S, Gammeltoft-Hansen T, and Cerone J (eds), *Tracing the Roles of Soft Law in Human Rights* (OUP 2016); Wettstein F, 'Normativity, Ethics, and the UN Guiding Principles on Business and Human Rights: A Critical Assessment' (2015) 14 Journal of Human Rights 162.

⁴⁰ Hunt P, 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' (11 August 2008) United Nations General Assembly, UN Doc A/63/263; Lee JY and Hunt P, 'Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines' (2012) 40 J.L. Med. & Ethics 220; Moon S, 'Respecting the Right to Access to Medicines: Implications of the UN Guiding Principles on Business and Human Rights for the Pharmaceutical Industry' (2013) 15 Health and Human Rights 32.

⁴¹ Jägers N (n 39) 159; Lagoutte S (n 39) 237; Moon S (n 40) 32; Leipziger D, *The Corporate Responsibility Code Book* (3rd edn, Greenleaf Publishing 2016) 141; Office of the United Nations High Commissioner for Human Rights (OHCHR), 'Guiding Principles on Business and Human Rights' (2011) UN Doc HR/PUB/11/04.

⁴² cf. Jägers N (n 39) 159; Lagoutte S (n 39) 235; Leipziger D (n 41) 141-142.

⁴³ OHCHR, 'Guiding Principles on Business and Human Rights' (n 41) 1.

acknowledge the importance of businesses applying the Guiding Principles as a means of tackling sustainable development challenges.⁴⁴

To a certain extent, the Guiding Principles are connected to an earlier attempt by the UN Sub-Commission on Human Rights to adopt a legally binding framework providing Norms on the Responsibility of Transnational Corporations and Other Business Enterprises with Regard to Human Rights, commonly referred to as the Draft Norms. After the implementation of the Draft Norms failed in the early 2000s, due to considerable objections from businesses and states, the international discussion on human rights responsibilities of non-state actors practically stagnated.⁴⁵ When taking up his mandate, Ruggie successfully managed to revive the debate.⁴⁶ To achieve a consensus this time round, the Guiding Principles follow a different approach based on a ‘principled pragmatism’ which is focussed on the consultation of various stakeholders and the willingness to accept compromises.⁴⁷ Therefore, rather than aspiring to the adoption of a legally binding framework that has proven to face considerable opposition in the international community, Ruggie took a moderated approach by drafting voluntary Guiding Principles aiming at the goodwill of the private business sector, and anticipating further legal developments in the future.⁴⁸ The Guiding Principles thus refrain from the creation of any directly binding legal obligations.⁴⁹ Nevertheless, the framework seems to be more extensive than common soft law policies, in that the guidelines suggest that all corporations have the elaborated responsibilities irrespective of their size or consent, or the consent of their home states.⁵⁰ While corporations are thus prompted to abide by international human rights law, the Guiding Principles notably lack the adoption of significant enforcement mechanisms, so that the framework itself remains strictly voluntary.⁵¹ Ruggie leaves the implementation of binding corporate human rights responsibilities and their enforcement to the willingness of domestic legislators.⁵² In this respect, the Guiding

⁴⁴ UNGA, UN Doc A/RES/70/1 (n 19) para 67.

⁴⁵ Jägers N (n 39) 159-160; Lagoutte S (n 39) 239; Wettstein F (n 39) 162.

⁴⁶ Jägers N (n 39) 159.

⁴⁷ Jägers N (n 39) 160; Wettstein F (n 39) 163 and 175.

⁴⁸ Wettstein F (n 39) 165.

⁴⁹ Lagoutte S (n 39) 239 and 243.

⁵⁰ Leipziger D (n 41) 143; Wettstein F (n 39) 165.

⁵¹ Barakat N (n 39) 592 and 613.

⁵² Lee JY and Hunt P (n 40) 223; Wettstein F (n 39) 166.

Principles can be regarded as an instruction to eager governments on how effective human rights responsibilities of corporations can be realised.

Thus, while the framework is drafted in a manner which can be misconceived in a way that suggests an extension of the scope of the applicability of human rights standards to non-state actors, factually, the international legal sphere remains unaltered.⁵³ Notably, the Guiding Principles explicitly state that they are not intended to create ‘new international law obligations’.⁵⁴ In this regard, a particular criticism of the framework is that it seems to have missed the opportunity of establishing directly legally binding obligations regulating the human rights responsibilities of corporations.⁵⁵ Ultimately, however, it must be acknowledged that Ruggie’s pragmatism and his abstention from the intention of creating legally binding obligations were key to the authoritative endorsement of the Guiding Principles by the HRC.

Nonetheless, the frequent use of the term ‘should’ by the principles indicates the weakness of the framework and the leeway left for corporations to circumvent their responsibilities.⁵⁶ Thus, the effective enforcement of the identified responsibilities requires states to act on a domestic level.⁵⁷ Unfortunately, even though the Guiding Principles remain largely focussed on the responsibility of states to effectively regulate the private business sector, the framework is frequently criticised for taking a weak approach to providing governmental obligations.⁵⁸ In this regard, it is submitted by Jägers that the Guiding Principles may be regarded as a step backwards.⁵⁹ Indeed, while the framework reinforces the duty of states to protect human rights, the weak terms adopted by the Guiding Principles risk diluting the significance of prior existing obligations of states under international human rights law.⁶⁰

Generally speaking, the underlying ‘protect, respect, and remedy’ terminology of the Guiding Principles provides that states have the duty to protect human rights, while

⁵³ Lagoutte S (n 39) 236.

⁵⁴ OHCHR, ‘Guiding Principles on Business and Human Rights’ (n 41) 1.

⁵⁵ Jägers N (n 39) 160; Leipziger D (n 41) 142.

⁵⁶ OHCHR, ‘Guiding Principles on Business and Human Rights’ (n 41) Guidelines 11-24; Wettstein F (n 39) 165.

⁵⁷ Jägers N (n 39) 162.

⁵⁸ *ibid* 160 and 162; Wettstein F (n 39) 165.

⁵⁹ Jägers N (n 39) 161.

⁶⁰ Barakat N (n 39) 600; Jägers N (n 39) 161; Lagoutte S (n 39) 236; Wettstein F (n 39) 165.

corporations have the mere responsibility of respecting human rights.⁶¹ The main element of the term ‘to respect’ is defined by the framework as a negative or passive responsibility of not infringing human rights, i.e. of doing no harm.⁶² This approach is often criticised for reducing the human rights responsibilities of the business sector to the absolute minimum, particularly in consideration of the vast political power of certain multinational corporations.⁶³ When regarded in relation to the comparatively marginal economic and political power of some developing countries, it becomes apparent that the responsibilities of corporations should go beyond the simple requirement of doing no harm.⁶⁴

On the other hand, according to Ruggie, the Guiding Principles are to be understood in a way in which the responsibility to not infringe human rights constitutes the general baseline to which all businesses should always adhere, in any given circumstances.⁶⁵ Thus, the concept of ‘respect’ entails additional responsibilities for corporations depending on the circumstances of specific situations, for example when a business fulfils crucial social functions.⁶⁶ It may therefore be suggested that in consideration of the vital public function of the pharmaceutical industry, pharmaceutical corporations have higher responsibilities than simply avoiding the commitment of human rights violations by their direct actions. These specific responsibilities of the pharmaceutical industry were explored by Paul Hunt in his Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines, elaborated in the next section.

5.1.3.2 Paul Hunt’s Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines

On 11 August 2008, Paul Hunt, then UN Special Rapporteur on the right to health, submitted a report to the UN General Assembly in which he elaborates a voluntary framework identifying responsibilities of pharmaceutical corporations towards the right to health. The framework recognises the assertion of senior public officials who

⁶¹ Lagoutte S (n 39) 235; Leipziger D (n 41) 142; Moon S (n 40) 33.

⁶² Jägers N (n 39) 162; Moon S (n 40) 35; Wettstein F (n 39) 169.

⁶³ Jägers N (n 39) 160; Wettstein F (n 39) 165 and 172.

⁶⁴ Wettstein F (n 39) 172.

⁶⁵ Lee JY and Hunt P (n 40) 223.

⁶⁶ Moon S (n 40) 35.

suggest that the implementation of the right to health is hampered by the policies and practices of certain pharmaceutical corporations, observing that particularly pricing policies and the neglect of research into diseases that mainly affect the poor, create severe obstacles for the accessibility of medicines.⁶⁷ For this reason, there is an urgent requirement to regulate the activities of the pharmaceutical industry and particularly their specific responsibilities towards the right to health. While it is generally accepted that states are the main duty bearers of human rights responsibilities, Hunt acknowledges Goal 8.E of the MDGS, reaffirming that the right to health entails a shared responsibility between states and pharmaceutical corporations.⁶⁸ Hunt further notes that while CESCR General Comment No 14 provides that non-state actors, including the private business sector, have certain responsibilities towards the right to health, the scope and dimension of these responsibilities is not further defined and therefore is unclear.⁶⁹ In this consideration, the Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines (Guidelines) address the pressing need of clearly identifying the human rights responsibilities of the pharmaceutical industry.⁷⁰

While accepting that from a technical perspective the human rights responsibilities of corporations cannot be the same as the obligations of states, Hunt elaborates that the pharmaceutical industry nevertheless has distinct responsibilities towards three of the main elements of the right to health; namely the availability, the accessibility and the affordability of medical products.⁷¹ Nevertheless, in order to be regarded as reasonable, the responsibilities of pharmaceutical corporations need to be balanced. Thus, in consideration of economic realities, it must be acknowledged that private corporations have responsibilities towards shareholders, including the derivation of profits.⁷² Hunt therefore suggests that while it is unreasonable to expect that corporations suffer cumulative losses, it may be adequate to suggest that

⁶⁷ Hunt P, UN Doc A/63/263 (n 40) para 23; Khosla R and Hunt P, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines: The Sexual and Reproductive Health Context* (University of Essex, 2008) 9.

⁶⁸ Hunt P, UN Doc A/63/263 (n 40) para 44.

⁶⁹ *ibid* para 26.

⁷⁰ *cf.* Khosla R and Hunt P (n 67) 9.

⁷¹ *cf.* Hunt P, 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of health – Annex: Mission to GlaxoSmithKline' (5 May 2009) United Nations General Assembly, UN Doc A/HRC/11/12/Add.2, paras 20-24.

⁷² *ibid* para 37; Khosla R and Hunt P (n 67) 11.

pharmaceutical corporations should operate on a non-profit model in respect of providing medicines to impoverished populations.⁷³

In his work as UN Special Rapporteur on the right to health, Hunt took on the task of debunking a common misconception of pharmaceutical corporations in which the research-based industry regards patents as the company's crown jewels.⁷⁴ While this may be true from an economic perspective, given the monetary value of patents, the granting of patents is subject to further considerations, including an essential social dimension.⁷⁵ By developing new, potentially life-saving medicines, pharmaceutical corporations perform honourable public health functions.⁷⁶ Patent rights awarded for the successful R&D activity of a pharmaceutical company can thus be regarded as a reward for the fulfilment of this vital social function.⁷⁷ As noted before, in chapter 4.4, the granting of patent rights entails an implicit social contract, according to which patent holders receive exclusive market positions, while the public has a reasonable expectation that corporations take positive actions towards enhancing the accessibility of their patented medicines.⁷⁸ In other words, the social dimension of the development of a new medicine, which is rewarded by patent rights, entails a corporate responsibility of making treatment accessible to patients.⁷⁹

Thus, in their general scope, the responsibilities of pharmaceutical corporations elaborated in Hunt's Guidelines go further than Ruggie's Guiding Principles in that they not merely address the importance of corporations respecting human rights, but rather explore specific responsibilities beyond the responsibility to respect.⁸⁰ At the same time, Hunt rests his framework on a robust interpretation of the responsibility to respect, elaborating specific actions contravening the right to health, which pharmaceutical corporations should forgo. Guideline 4, for instance, provides that pharmaceutical corporations should refrain from encouraging states to disregard their

⁷³ Hunt P, UN Doc A/HRC/11/12/Add.2 (n 71) para 39.

⁷⁴ *ibid* para 107.

⁷⁵ *ibid*.

⁷⁶ *ibid* para 35.

⁷⁷ *ibid*.

⁷⁸ *ibid* paras 36-37 and 41; Khosla R and Hunt P (n 67) 5.

⁷⁹ Khosla R and Hunt P (n 67) 11.

⁸⁰ Lee JY and Hunt P (n 40) 224.

human rights obligations under national and international law.⁸¹ To this end, the Guidelines emphasise that the lobbying activity of the pharmaceutical industry should not be directed at the creation of stronger patent protection standards than those provided for under TRIPS.⁸² In particular, corporations should refrain from lobbying in LDCs with the aim of persuading low-income countries to comply with international patent standards before the end of the transitional periods provided to them by the WTO.⁸³ Furthermore, the Guidelines reemphasise the importance of the Doha Declaration by acknowledging that the private business sector has a responsibility to respect the declaration, and that corporations should consequently refrain from imposing economic sanctions on states that justifiably utilise the Doha Declaration's export solution, now regulated by Article 31*bis* TRIPS, as elaborated in chapter 2.4.3.8.⁸⁴

In addition to these provisions addressing the negative responsibility of businesses to respect human rights, the Guidelines provide positive responsibilities for pharmaceutical corporations towards the realisation of the right to health. Notably, in consideration of the availability of medicines, Hunt identifies two dimensions of the responsibilities of corporations. Firstly, medicines should be made 'available in sufficient quantities in the countries where they are needed.'⁸⁵ This implies, *inter alia*, that the distribution of medicines should not be arbitrarily declined to specific countries, for example as an economic sanction in retaliation of insufficient domestic IP protection standards.⁸⁶ Secondly, the availability of medicines requires that adequate research is conducted into the development of new medical products. In this regard, the Guidelines recognise that in particular current incentives for the development of drugs for the treatment of neglected diseases are insufficient, and that therefore pharmaceutical corporations should commit to conducting research into highly needed medications for the poor.⁸⁷

⁸¹ Hunt P, 'Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines' (11 August 2008) in the Annex to the 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health', United Nations General Assembly, UN Doc A/63/263, Guideline 4.

⁸² *ibid* Guideline 26.

⁸³ *Ibid* Guideline 29.

⁸⁴ *ibid* Guidelines 27-28.

⁸⁵ Lee JY and Hunt P (n 40) 225.

⁸⁶ *cf. ibid.*

⁸⁷ Hunt P, 'Human Rights Guidelines for Pharmaceutical Companies' (n 81) Guidelines 23-25.

In this consideration, Guideline 5 addresses the special requirements of disadvantaged individuals, communities, and populations, emphasising that pharmaceutical corporations should pay due regard to the needs of the most vulnerable, particularly with regard to people living in severe poverty.⁸⁸ In respect of the accessibility and the affordability of medicines, this implies that pharmaceutical corporations should ensure that their medical products are accessible to everyone, including populations living in rural areas.⁸⁹ Furthermore, the pricing strategies of pharmaceutical corporations should ensure that their medicines are affordable for people living in poverty.⁹⁰ Similarly, in recognition of the impact of patents on the prices of medical products, Guideline 32 encourages research-based pharmaceutical corporations to refrain from filing patents for marginal advancements of prior existing drugs, such as new uses or new dosages.⁹¹

Lastly, it is to note, that similar to Ruggie's Guiding Principles, Hunt's Guidelines adopt the term 'should' rather than 'must' when elaborating on the responsibilities of corporations in order to avoid controversial doctrinal issues, which indicates that adherence to the framework is voluntary.⁹² In this regard, in a response to a report submitted to the UN General Assembly by Hunt in his role as Special Rapporteur on the right to health, summarising his visit to GSK, the company contested the existence of any international legal norms arising from the Guidelines.⁹³ While preparing the Guidelines, Hunt visited the headquarters of GSK in June 2008 to prepare a report examining the company's policies regarding the right to health, particularly focussing on the accessibility of medicines in developing countries.⁹⁴ In June 2009, his report was presented to the UN Human Rights Council, and although GSK wished to respond to the report, permission to speak was not granted by the UN.⁹⁵ In this regard, GSK provided a written statement in which it welcomed the engagement of Hunt, and expressed an interest in reviewing the report.⁹⁶ The company further noted the importance of the right to health, but expressed that private actor responsibilities are not sufficiently defined by international human rights law.⁹⁷ In this consideration, GSK

⁸⁸ *ibid* Guideline 5.

⁸⁹ *ibid* Guideline 33; Lee JY and Hunt P (n 40) 225.

⁹⁰ Hunt P, 'Human Rights Guidelines for Pharmaceutical Companies' (n 81) Guideline 33.

⁹¹ *ibid* Guideline 32.

⁹² Hunt P, UN Doc A/63/263 (n 40) para 46; Khosla R and Hunt P (n 67) 12.

⁹³ Lee JY and Hunt P (n 40) 231.

⁹⁴ Hunt P, UN Doc A/HRC/11/12/Add.2 (n 71) Summary.

⁹⁵ Lee JY and Hunt P (n 40) 231.

⁹⁶ *ibid*.

⁹⁷ *ibid*.

emphasised that its access to medicines programme and ongoing commitment is not required by international legal norms.⁹⁸

5.1.4 The Insufficiency of Voluntary Frameworks

First and foremost, it must be acknowledged that both Hunt and Ruggie conducted remarkable work in reviving the stagnating debate on the human rights responsibilities of non-state actors, providing two of the most authoritative frameworks identifying and elaborating on specific responsibilities. These frameworks reinforce the notion that corporations have direct responsibilities under international human rights law, and in particular identify those responsibilities which the International Bill of Rights and the various CESCR General Comments left undefined. The strongest trait of the approach taken by Hunt and Ruggie is to be seen in the drafting of non-binding soft law instruments which may be regarded as the essential key to receiving the endorsement of the UN, and thereby for the establishment of internationally recognised responsibilities. This trait, however, simultaneously constitutes the greatest weakness of the frameworks in that adherence to the Guidelines and Guiding Principles remains strictly voluntary for corporations. Thus, the frameworks may suffer the same fate of being neglected as international human rights law, when the soft law responsibilities of the private business sector stand in conflict with the rights of corporations under more strongly worded international trade law treaties, particularly when monetary interests are at stake.

The main problem with soft law instruments in this regard is that while they may have political implications for governments, their direct effect on corporations seems to be far less stringent.⁹⁹ According to Lagoutte, the Guidelines and the Guiding Principles dress CSR in the language of international law, thereby creating the illusion that there is a binding effect attached to them, ‘while in fact CSR stays within the realm of voluntary commitments by business enterprises.’¹⁰⁰ Due to the very nature of voluntary measures, the adherence of private businesses to their human rights responsibilities

⁹⁸ *ibid.*

⁹⁹ Lagoutte S (n 39) 236.

¹⁰⁰ *ibid* 247.

remains subjected to the goodwill of individual corporations.¹⁰¹ As can be observed throughout this thesis, economic realities suggest that monetary interests are commonly the primary concern of private companies, so that the willingness of corporations to voluntarily observe social objectives is heavily dependent on concomitant potential negative impacts on their profitability.¹⁰² As corporations have a direct obligation towards their shareholders of maximising economic returns, voluntary human rights responsibilities, which are likely to result in considerable reductions of profits, are prone to being ignored.¹⁰³ This is of particular concern in regard to the right to health, as reducing the prices of medical products, in order to make them more widely accessible to patients living in poverty, entails significant reductions of the profitability of pharmaceutical corporations. Thus, as long as the maximisation of profits is underlying the business model of the pharmaceutical industry, monetary interests will presumably trump human rights objectives.¹⁰⁴

On the other hand, soft law instruments cannot be considered as downright ineffective, as the identification of non-binding responsibilities offers the opportunity of finding fast-track solutions to pressing issues, which, while not being *a priori* binding, may constitute an important step towards the future development of binding regulations.¹⁰⁵ Furthermore, soft law instruments offer a certain degree of protection as the possibility of detrimental impacts on public opinion resulting from the omission of human rights responsibilities may encourage corporations to observe non-binding standards. The effectiveness of the human rights protection provided by public opinion, however, is contested. Wettstein suggests that powerful vocal stakeholders, for instance, have distinct advantages over vulnerable and marginalised populations which commonly lack the opportunity of voicing their concerns, and thereby shaping public opinion in their favour.¹⁰⁶ Thus, leaving the enforcement of corporate responsibilities to a domain that is heavily influenced by its most powerful actors seems to contravene the very purpose of human rights law itself, namely the protection of vulnerable groups against the abuse of power.¹⁰⁷

¹⁰¹ Wettstein F (n 39) 173.

¹⁰² cf. *ibid* 176.

¹⁰³ Moon S (n 40) 39.

¹⁰⁴ cf. Wettstein F (n 39) 176.

¹⁰⁵ Lagoutte S (n 39) 252-253.

¹⁰⁶ Wettstein F (n 39) 176.

¹⁰⁷ *ibid*.

Thus, in recognition of the crucial importance of the right to health for safeguarding human life in dignity, an answer to Research Question 4 can be provided:

Why is the corporate social responsibility approach to identifying human rights responsibilities of the private business sector in non-binding international soft law instruments insufficient for adequately regulating the pharmaceutical industry's conduct towards the right to health?

The direct implications of the realisation of the right to health on the lives and livelihood of millions of people around the globe are of such magnitude that the adherence to responsibilities for its respect and protection must not simply be regarded as a voluntary option. In view of the historical evidence, leaving the realisation of the accessibility of medical products, as an integral part of the right to health, to the goodwill of the pharmaceutical industry has proved to be insufficient, as can be concluded from the scope of this thesis. The first thing to remember is that the right to health competes with conflicting IP rights provided under strongly worded international trade law treaties, which enable pharmaceutical corporations to act in accordance with a business model that almost unreservedly favours their own corporate interests. As the maximisation of profitability in order to enhance shareholder value can be regarded as one of the primary aims of the research-based industry, human rights concerns are likely to only ever receive marginal consideration in corporate policies. This issue is highly unlikely to be changed by the adoption of non-binding soft law instruments that keep the human rights responsibilities of profit driven corporations in the realm of voluntarism.

It can thus be submitted that while the adoption the UN Guiding Principles on Business and Human Rights and the Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines constitutes major steps forward, both instruments missed the opportunity of establishing the strongly drafted binding obligations which would be required for inducing actual change. Corporations that refuse to acknowledge their human rights responsibilities thus do not have much to fear, so that there remains a real risk that private businesses will only ever be inclined to do the bare minimum.¹⁰⁸ Consequently, the effectiveness of these frameworks intrinsically depends on considerable governmental action in enacting binding domestic legislation, and the

¹⁰⁸ cf. Jägers N (n 39) 163.

willingness of states to enforce the human rights responsibilities of the private business sector.¹⁰⁹

Ultimately, however, it must be acknowledged that both Hunt and Ruggie were successful in getting their frameworks endorsed by the UN, especially because they took the voluntary, non-binding soft law approach. The fact that the UN-Sub Commission on Human Rights failed in their attempt to adopt a legally binding framework on corporate human rights responsibilities in the early 2000s proves just how difficult it is to find consensus on binding obligations in the realm of international human rights law. In regard to the pharmaceutical industry, however, the very patentability of medical products itself opens up a different approach for regulating the responsibilities of patent holding corporations. While patents currently severely impact on the affordability of medicines, they also offer an opportunity for implementing specific responsibilities of corporations in hard law international trade agreements, as will be elaborated in the next section.

5.2 Suggested Amendments to the TRIPS Agreement: Implementing Responsibilities of the Pharmaceutical Industry as Obligations under International Patent Law

In recognition of the shortcomings of soft law instruments when it comes to the enforcement of corporate human rights responsibilities, a different approach to the implementation of responsibilities of the private business sector seems to be required. In this regard, the second part of this chapter explores the possibilities of introducing distinct responsibilities for private actors as explicit obligations under international patent laws. In doing so, this section provides an answer to Research Question 5:

Can responsibilities of pharmaceutical patent holders towards the realisation of the right to health be implemented into the TRIPS Agreement in order to establish a balance between private interests and public health, thereby enhancing the justification of the international patent regime?

In the first place, it must be acknowledged that the aforementioned voluntary principles constitute a progressive step in the right direction for identifying the general

¹⁰⁹ cf. Moon S (n 40) 39-40.

human rights responsibilities of the private business sector. This chapter therefore is not aimed at contesting the possibility that soft law principles regulating corporate human rights responsibilities may have considerable positive impacts on the general realisation and protection of human rights in a variety of fields and sectors. An analysis of these impacts, however, is not encompassed by the scope of this thesis. In the pharmaceutical sector, the situation is distinctively different from other business sectors in that the provision of exclusive private patent rights to corporations itself constitutes a major threat to the realisation of the right to health, particularly when those private rights are not sufficiently balanced with public health interests. As pharmaceutical patents thereby directly impact on human health and the capability of human beings to achieve a life in dignity, the realisation of the right to health should not simply be left to the benevolence of corporations, and their willingness to abide by voluntary guidelines. It is therefore submitted that in regard to the patentability of pharmaceutical products the right approach is not about identifying generalised human rights responsibilities of the private business sector, but about defining specific responsibilities of patent holders which arise from the provision of a patent itself. In other words, in order for the right to health to be realised and not obstructed by the provision of patents, it is crucial to define the social responsibilities of patent holders that are implicitly connected to the granting of exclusive rights.

With this in mind, it is suggested that the nature of patent laws provides a distinct opportunity for implementing binding responsibilities of corporations in international trade law instruments. Notably, this is facilitated by the granting of desirable patent rights to successful inventors in the pharmaceutical sector, as the provision of those rights can be subjected to concomitant obligations. The human rights responsibilities of the research-based industry can thereby be turned into legally binding obligations. Therefore, the enforcement of corporate responsibilities can be executed by making the adherence to relevant obligations a requirement for patentability, and non-compliance a reason for the revocation of a patent. Comparatively, this approach is considerably more radical than the strategy of identifying voluntary corporate human rights responsibilities in soft law instruments. However, the controversial doctrinal issues arising when aiming for the implementation of general business responsibilities in the realm of public international human rights law, which is traditionally only directly applicable to states, can be avoided by instead seeking the direct introduction

of corporate obligations into private international trade law. In particular, this can be achieved by subjecting the provision of valuable private rights to the compliance with concomitant responsibilities.

Furthermore, this approach seems to be legally desirable under human rights law considerations, as, by implementing binding corporate obligations and thereby effectively regulating the activities of third parties, states would eventually meet their duties to fulfil and protect human rights against abuses by third parties. In recognition of the UN Guiding Principles on Business and Human Rights, which reemphasise the duties of states to protect and fulfil human rights under international law, it can be deduced that states are required to ensure that international trade agreements are compatible with the right to health under international human rights law.¹¹⁰ The ratification of an agreement such as TRIPS, and the adoption of any TRIPS-Plus agreements, which fail in safeguarding prior existing human rights law, may in fact constitute a violation of those conventions.¹¹¹ It is suggested here that such a violation can only be averted by the implementation of provisions which explicitly balance private economic rights with public human rights requirements.¹¹² Consequently, it can be suggested that an amendment of the TRIPS Agreement is required under international human rights law in order for states to fulfil their right to health obligations.¹¹³

Although this may be true, in the international political landscape any proposed amendment to a large-scale trade agreement is likely to face vigorous opposition, so that finding sufficient support for revising the TRIPS Agreement may entail considerable difficulties.¹¹⁴ In particular, opposition from the US may constitute a severe obstacle for any attempt at lowering IP protection standards, as the US has never formally ratified the ICESCR. Therefore, the US can exclude itself from the obligation of states to pay due regard to the right to health in international agreements.¹¹⁵

¹¹⁰ cf. Lagoutte S (n 39) 238; Moon S (n 40) 41.

¹¹¹ Beiter KD, 'Establishing Conformity Between TRIPS and Human Rights: Hierarchy in International Law, Human Rights Obligations of the WTO and Extraterritorial State Obligations Under the International Covenant on Economic, Social and Cultural Rights' in Ullrich H and others (eds), *TRIPS Plus 20 - From Trade Rules to Market Principles* (Springer 2016) 478.

¹¹² cf. Haugen HM, 'Human Rights and TRIPS Exclusions and Exception Provisions' (2009) 11 JWIP 345, 359.

¹¹³ Beiter KD (n 111) 499.

¹¹⁴ *ibid* 478.

¹¹⁵ cf. Helfer LR, 'Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking' (2004) 29 Yale Journal of International Law 1, 61.

Additionally, the lobbying activity of the powerful research-based pharmaceutical industry may create further obstacles to overcome when aiming for a weakening of protection standards in the international patent regime. That it is nevertheless possible to amend the TRIPS Agreement is evidenced by the successful first-ever adoption of an amendment implementing Article 31*bis* TRIPS which entered into force in 2017, as elaborated in chapter 2.4.3.8. This recent amendment indicates that states may become more willing to regulate IP laws in a manner conducive to the right to health.

For these reasons, the following sections of this chapter consider potential methods of how the TRIPS Agreement can be amended in order to bring it in line with international human rights requirements. First, sub-chapter 5.2.1 examines a proposed amendment text launched by the ‘Intellectual Property Rights in Transition’ Project, providing suggestions for a general amendment to the TRIPS Agreement. Second, in sub-chapter 5.2.2, I suggest a different approach to amending the TRIPS Agreement, focussing only on a specific revision of the patentability of pharmaceutical products in regard to the right to health.

5.2.1 The Proposed Amendment Text by the ‘Intellectual Property Rights in Transition’ Project

The following section of this thesis provides a brief analysis of some of the key suggestions made by the ‘Intellectual Property Rights in Transition’ Project (IPT Project) in respect of international patent laws in a proposed amendment to the TRIPS Agreement. Launched by the University of Stockholm’s Institute for Intellectual Property and Market Law (IFIM), in collaboration with the Max Planck Institute for Intellectual Property, Competition and Tax Law in Munich, the University of Copenhagen’s Institute for Civil Law, and the IPR University Center in Helsinki, the IPT Project was coordinated by Marianne Levin and Annette Kur, joined by a considerable number of scholars and experts in the field of international IP law.¹¹⁶ The rationale behind the project was to address the impacts of international IP rights on public welfare, and the growing scepticism towards unreasonably high IP protection

¹¹⁶ IPT Project, ‘Explanatory Memorandum’ in Kur A and Levin M (eds), *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS* (Edward Elgar 2011) 526.

standards, particularly in respect of distinct negative consequences on ‘sensitive issues such as public health, nutrition, and the dissemination of knowledge.’¹¹⁷ The work of the IPT Project culminated in the proposition of a substantial amendment to the text of the TRIPS Agreement, suggesting a revision of seemingly deficient IP provisions, and the implementation of adequate mechanisms for balancing private exclusive rights with public societal interests.¹¹⁸

From an overall view, it can be observed that the IPT Project adopts a moderated and broad approach to revising the TRIPS Agreement. Thus, while addressing all sections of the agreement, including proposals for the amendment of patent rights in general, the proposed amendment holds back on providing specific regulations tailored to the issues surrounding the patentability of pharmaceutical products. Nevertheless, the approach taken by the IPT Project can be regarded as sensible. Ultimately, if implemented, the proposed amendment would potentially significantly improve the international IP regime by extending the capability of governments to act in accordance with their human rights duties without necessarily violating their obligations under international IP law. For the purpose of this thesis, this section briefly elaborates on the benefits and short comings of the IPT Project’s proposal, particularly focusing on the suggested amendments to objectives and principles of TRIPS in Articles 7 and 8, and the proposed revision of Articles 27 and 30 in the patent section of TRIPS.¹¹⁹

5.2.1.1 Proposed Amendments to the Objectives and Principles in Articles 7 and 8 TRIPS

In recognition of the crucial importance of the objectives and purposes of the TRIPS Agreement for the establishment of an adequately balanced IP regime, the IPT Project proposes a number of substantial changes to the wording of Articles 7 and 8 TRIPS, as well as the introduction of two new provisions in Articles 8a and 8b.¹²⁰ In general

¹¹⁷ *ibid* 526.

¹¹⁸ *cf.* *ibid* 526-527.

¹¹⁹ For an analysis of the current objectives and principles of the TRIPS Agreement, see chapter 2.4.2.3. For an analysis of Articles 27 and 30 TRIPS, see chapter 2.4.3.1, and chapter 2.4.3.6.

¹²⁰ IPT Project, ‘Proposed Amended Text (synopsis)’ in Kur A and Levin M (eds), *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS* (Edward Elgar 2011) 463-467.

consideration of the objectives of the international harmonisation of IP laws, it is submitted that Article 7 of the current TRIPS Agreement cannot be regarded as completely inadequate. Notably, the objectives of the agreement explicitly recognise the importance of providing mutual advantages for both producers and users of technological knowledge, and of enhancing social and economic welfare by balancing rights and obligations.¹²¹ The IPT Project, on the other hand, more strongly emphasises public objectives by placing social and economic welfare at the core of an amended Article 7, explicitly recognising that IP rights should take ‘due account of the larger public interest’.¹²² Furthermore, the proposed amendment of Article 7 provides a qualification for the balancing of rights and obligations, suggesting that IP protection shall be in proportion to the contribution made by an invention towards both innovation and society at large.¹²³ In this regard, it is suggested that incremental innovations should not be protected by the provision of strong exclusive rights.¹²⁴ The implementation of this provision, however, seems particularly problematic with respect to the 20-year minimum patent period provided by TRIPS, and the introduction of secondary patents for new uses and new dosages of medications under TRIPS-Plus FTAs. Thus, to be effectively realisable, the non-patentability of incremental innovations requires substantive amendments to the term of protection provided by Article 33 TRIPS, which is not further addressed by the IPT Project. All things considered, it can be submitted that the proposed amendment of Article 7 TRIPS adds weight to the importance of public societal interests and the necessity of establishing an adequate balance in the overall objectives of all IP rights under TRIPS. In regard to the impacts of patents on public health, however, these objectives nevertheless require the support of distinct regulations in the patent section of TRIPS, addressing the specific issues associated with the patentability of medicines.

Addressing Article 8 TRIPS, the IPT Project proposes changes to the language and expressions adopted by the TRIPS Agreement in the identification of the underlying principles. For example, rather than stipulating that WTO members *may* adopt

¹²¹ Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (signed 15 April 1994, entered into force 1 January 1995) [TRIPS Agreement], Article 7.

¹²² IPT Project, ‘Proposed Amended Text’ (n 120) 463-464; IPT Project, ‘Explanatory Memorandum’ (n 116) 529.

¹²³ IPT Project, ‘Proposed Amended Text’ (n 120) 464; IPT Project, ‘Explanatory Memorandum’ (n 116) 531.

¹²⁴ IPT Project, ‘Explanatory Memorandum’ (n 116) 531.

measures for the protection of public health, the proposed amendment suggests the wording that members *should* adopt measures for the protection of public health.¹²⁵ While it is submitted that the suggested amendment provides beneficial improvements to the elaboration of the basic principles in Article 8 TRIPS, a detailed analysis of the linguistic intricacies goes beyond the scope of this thesis. For a detailed explanation of the proposed amendment of Article 8 see the IPT Project's 'Proposed Amended Text (synopsis)'¹²⁶ and the IPT Project's 'Explanatory Memorandum'.¹²⁷

Additionally, The IPT Project's amendment suggests the introduction of a specific balancing clause in a newly proposed Article 8a.¹²⁸ The proposed provision, entitled 'Balance of Interests', is of particular importance in that it strengthens the binding force of Article 7 and 8 by explicitly reaffirming their applicability to the specific IP provisions of Part II of the TRIPS Agreement.¹²⁹ Paragraph 1 of the proposed Article 8a reads:

Members shall take due account of the objectives and principles set out in Articles 7 and 8 when formulating or amending their laws and regulations. In doing so, they shall ensure that the protection granted reflects a fair balance between private economic interests and the larger public interest as well as the interests of third parties.¹³⁰

To stipulate that the establishment of an adequate balance is an integral requirement under the TRIPS Agreement, and thus not merely optional, the proposal specifically adopts the mandatory term 'shall' rather than the more moderated expression 'should'.¹³¹ In summary, it can thus be concluded that the suggested introduction of Article 8a can effectively tackle the issue that the objectives and principles of Articles 7 and 8 TRIPS were frequently neglected in the past, particularly in consideration of the patentability of medical products, as elaborated in chapter 4.3. It is therefore submitted that this provision should be implemented in any future amendment proposal to the TRIPS Agreement, irrespective of whether further amendments to the general scope of Articles 7 or 8 TRIPS are considered.

¹²⁵ IPT Project, 'Proposed Amended Text' (n 120) 464.

¹²⁶ See: IPT Project, 'Proposed Amended Text' (n 120) 464-465.

¹²⁷ See: IPT Project, 'Explanatory Memorandum' (n 116) 534-538.

¹²⁸ *ibid* 538.

¹²⁹ See: *ibid* 538-539.

¹³⁰ IPT Project, 'Proposed Amended Text' (n 120) 465.

¹³¹ IPT Project, 'Explanatory Memorandum' (n 116) 539.

5.2.1.2 Proposed Amendments to the Patentable Subject Matter under Article 27 TRIPS

In respect of specific patent provisions as regulated in Section 5 of Part II TRIPS, the IPT Project proposes an amendment to Article 27 TRIPS on Patentable Subject Matter which substantially changes the scope of this provision. While keeping the requirement that patents shall be available for inventions in all fields of technology, the proposed amendment abolishes the respective non-discrimination principle, as discussed in chapter 2.4.3.1.¹³² Article 27 would thus only prohibit discrimination as to the place of invention, meaning that differential treatment of patents in specific fields of technology, such as pharmaceutical products, would be permissible.¹³³ This is deemed necessary, as the current ‘one size fits all’ approach has proven to be insufficient for addressing the specific intricacies of certain technological sectors, so that appropriate patent regulations for individual fields of technology are required, particularly in the field of pharmaceuticals.¹³⁴ Furthermore, the proposed amendment of Article 27 abolishes the non-discrimination principle as to the place of production of patented products.¹³⁵ In other words, under the proposed amendment, governments have the freedom to implement a local working requirement in national patent laws, thereby effectively attracting foreign direct investments (FDI) into the establishment of domestic production facilities.¹³⁶ Notably, this proposal gives effect to the objectives and principles of the TRIPS Agreement, particularly in that it adequately facilitates the transfer of technology, the dissemination of knowledge, and technological capacity building in developing countries.¹³⁷

As can be seen, the IPT Project addresses some of the most problematic issues arising from the TRIPS Agreement’s patentability standards of Article 27 in respect to both public health and technological capacity building in developing countries. The proposed amendment, however, refrains from introducing further specific regulations on these issues. Consequently, the exact construction of domestic strategies is left for states and national legislators, which entails the risk that pressure from industry

¹³² IPT Project, ‘Proposed Amended Text’ (n 120) 490.

¹³³ *ibid.*

¹³⁴ IPT Project, ‘Explanatory Memorandum’ (n 116) 580.

¹³⁵ IPT Project, ‘Proposed Amended Text’ (n 120) 490.

¹³⁶ IPT Project, ‘Explanatory Memorandum’ (n 116) 582.

¹³⁷ *ibid* 582.

lobbyists and detailed provisions in TRIPS-Plus FTAs may prevent states from adopting adequate policies. Moreover, by enabling the differential treatment of different fields of technology without providing any qualification or protective measures, the amended Article 27 may facilitate a potential push by the research-based industry towards even stricter protection of pharmaceutical patents.

5.2.1.3 Proposed Amendment to the Exceptions under Article 30 TRIPS

The IPT Project's amendment to the patent section of TRIPS, additionally proposes extensive changes to Article 30, which is discussed in chapter 2.4.3.6, essentially redesigning the entire scope and content of this provision. To begin with, this proposal suggests a distinct amendment of the title of Article 30, replacing the notion of 'Exceptions to the Rights Conferred' with 'Limitations', indicating that this regulation shall not be regarded as providing mere exceptions to the general rule, but that the limitations provided are intrinsic to all patent rights.¹³⁸ In this regard, paragraph 1 of the proposed Article 30 amendment suggests a number of mandatory limitations, enumerating acts and uses which shall not be encompassed by the protection conferred by patents.¹³⁹ Accordingly, the new regulation can be regarded as a type of 'ceiling rule', setting transparent and clear upper limits to the extent of patent protection standards.¹⁴⁰ These limitations, inter alia, exempt from patent protection the use of an invention as necessary for engaging in reverse engineering, experimentation with the aim of improving an invention, and experimentation for the purposes of submitting data for the marketing approval of products entering the market after a patent expires.¹⁴¹ Furthermore, in respect of pharmaceutical patents, paragraph 1(e) of the proposed Article 30 provides that patents shall not prevent pharmacies from preparing extemporaneous medicines for individual prescriptions.¹⁴² The rationale behind this limitation is that pharmacists should not be subject to patent infringement when providing individual patients with on-demand preparations according to the

¹³⁸ cf. IPT Project, 'Proposed Amended Text' (n 120) 493.

¹³⁹ IPT Project, 'Proposed Amended Text' (n 120) 493; IPT Project, 'Explanatory Memorandum' (n 116) 584.

¹⁴⁰ IPT Project, 'Proposed Amended Text' (n 120) 493; IPT Project, 'Explanatory Memorandum' (n 116) 585.

¹⁴¹ IPT Project, 'Proposed Amended Text' (n 120) 493.

¹⁴² *ibid.*

prescription of doctors.¹⁴³ This is the only limitation provided by the amendment that explicitly addresses issues regarding the accessibility of medicines, so that it is submitted that the proposed limitations to the rights conferred are not sufficiently equipped for safeguarding that pharmaceutical patents will not interfere with the realisation of the right to health.

Paragraph 3 of the proposed amendment to Article 30, on the other hand, suggests the implementation of an explicit authorisation for WTO member states ‘to further restrict the protection conferred by patents’ in accordance with the proposed amendments to the objectives and principles of the TRIPS Agreement.¹⁴⁴ This provision would enable governments to adopt measures limiting patent rights as necessary for the protection of public health. Paragraph 3 of Article 30 would thus facilitate a balanced implementation of the patent provisions of TRIPS, enabling states to limit pharmaceutical patent protection where this protection would conflict with the interests of society at large. While in general, this seems to be a sensible approach to safeguarding public health objectives, the proposed amendment refrains from defining the scope of legitimate measures available to states. On the one hand, this provides governments with considerable freedom in designing measures adequate to their individual needs. On the other hand, however, such measures may be subject to legal scrutiny, as the industry is likely to contest any policy adopted by governments, which is not explicitly recognised by the TRIPS Agreement. Industry representatives may further persuade governments to refrain from the adoption of such measures all together. Lastly, the open manner in which paragraph 3 is formulated insinuates that public health remains an exception to patent rights, rather than a limitation thereof. As noted in chapter 4.2.3, however, human health is of such crucial importance for human dignity that its protection should never be just an exception to private economic rights.

5.2.1.4 Concluding Remarks

All things considered, the proposed amendment by the IPT Project emphasises the necessity of balancing public and private interests, and suggests valuable improvements to some of the key provisions of TRIPS that impact on the capability of

¹⁴³ IPT Project, ‘Explanatory Memorandum’ (n 116) 591.

¹⁴⁴ IPT Project, ‘Proposed Amended Text’ (n 120) 494.

WTO member states to take measure for the protection of public health. The proposed amendment therefore constitutes an important step in the right direction, indicating how some of the most detrimental impacts caused by the current international patent regime can be alleviated. Nevertheless, while acknowledging the distinct value of the proposed amendment, and without the intention of being dismissive of its laudable contribution, it can be suggested that the IPT Project took a moderate approach, in that it refrains both from making clear human rights references and from elaborating direct obligations of patent holders towards public interests. In this respect, it is particularly regrettable that while the amendment to Article 7 suggests that the protection conferred by IP rights shall be proportionate to the actual positive contribution of an invention, the proposal leaves the general minimum patent period of 20 years under Article 33 TRIPS completely unaddressed. Similarly, the proposed amendment refrains from specifically engaging with patentability requirements, reasons for revocation, and the protection of undisclosed information in Section 7 of Part II of the TRIPS Agreement. Ultimately, it can be concluded that while the proposed amendment provides a sensible approach to updating some of the controversial issues arising from the TRIPS Agreement, certain distinct concerns in regard to the patentability of pharmaceutical products remain unattended. Therefore, especially focussing on pharmaceutical patents and the realisation of the right to health, the next section of this thesis considers a different approach to amending the TRIPS Agreement, exploring the possibility of conditioning the award and revocation of patent rights to the adherence to specific concomitant obligations.

5.2.2 Proposed Revisions of the Patentability Standards for Pharmaceutical Products Linking Distinct Obligations to the Rights Conferred

To adequately contribute to the realisation of the right to health, the patent section of the TRIPS Agreement urgently requires a more substantial amendment than that suggested by the IPT Project. While any more radical approach is also more likely to encounter additional difficulties and obstacles than a moderated approach when seeking global implementation, the author submits that the patentability of

pharmaceutical products itself provides unique parameters in this field that sensibly facilitate the consideration of ambitious amendments.

Research-based pharmaceutical corporations seek desirable protection for their inventions in the form of exclusive patent rights that provide inventors with the capability of receiving monopoly rents on the markets. The provision of a patent is subject to the fulfilment of certain patentability requirements which currently specify mere technicalities that need to be fulfilled in order for an invention to qualify as a patentable innovation. According to the objectives of the TRIPS Agreement, on the other hand, IP rights shall be further balanced with obligations of rights holders. At the present time, however, the patent section of the TRIPS Agreement fails to stipulate any distinct obligations associated with the provision of patent rights. Therefore, the implementation of obligations is urgently required. Patent rights should thus be subjected to specific obligations of rights holders, with non-compliance constituting a reason for the revocation of a patent. It can be assumed that the research-based pharmaceutical industry would adhere to such obligations, as patent rights provide corporations with a valuable means for recouping R&D investments and realising substantial profits. Consequently, depending on the willingness of the international community, the nature of patents provides an opportunity for implementing right to health obligations directly into international patent laws.

At the same time, it must be ensured that these obligations are adequately balanced with patent rights, as excessive obligations may render pharmaceutical patents unattractive for the industry. Innovative corporations could then be inclined to refrain from filing patent applications, with the repercussion that the composition of new medicines remains undisclosed. This, on the other hand, would enable other pharmaceutical corporations, and particularly the generic industry, to engage in reverse engineering. Furthermore, the disclosure of an innovation is ultimately required for the purposes of marketing approval, so that governments retain a certain leeway when contemplating the introduction of distinct obligations for balancing the provision of patent rights.

The rationale behind the following proposed revision to the patent section of TRIPS is based on unique opportunities offered by the patentability of pharmaceutical products in consideration of its adverse impacts on the protection of public health. It is therefore

not suggested that a similar approach would be suitable for implementing corporate human rights responsibilities for patent holders in other sectors, or IP rights holders more generally. Although similar amendments may be possible, such considerations exceed the scope of this thesis. In this respect, the revisions proposed in the following sections are solely focussed on addressing the specific issues arising from the provisions of pharmaceutical patents.

The proposed revision of TRIPS is based on the acknowledgement that the current international patent regime is not justified. Consequently, amendments are required that balance the provision of private exclusive rights with the broader public interest. In this respect, egalitarian moral reasoning suggests that human rights concerns need to be duly regarded, particularly when human dignity is at stake. Consequently, private economic rights must not constitute obstacles for the realisation of human rights, but should instead contribute to their achievement. According to Gewirth's Principle of Generic Consistency, as elaborated in chapter 3.2.2.3, it can thus be submitted that the responsibilities of corporations towards the right to health go beyond the mere 'doing no harm' requirement of the responsibility to respect human rights. On the contrary, patent holders should be expected to take reasonable steps towards ensuring the accessibility of their patented medicines for all patients in need, and should further adequately contribute to the development of new pharmaceuticals. Not all human rights requirements, however, can be reasonably expected to be fulfilled by the private business sector, as the realisation of the right to health, for example, requires cheap medications, which, in order to be affordable by every person, potentially need to be distributed at prices below their production costs.

The following sections therefore elaborate on corporate responsibilities that can be sensibly implemented into the international patent regime in order to establish a reasonable balance between private and public rights and obligations. The proposed revisions are indicative of a feasible approach to amending the TRIPS Agreement in respect of right to health concerns without providing an elaborate amendment text.¹⁴⁵ The drafting of such a concrete amendment text ultimately needs to be conducted by a diverse working group consisting of both IP and Trade Law specialists as well as

¹⁴⁵ Because of the constraints and limitations of this thesis, this chapter only provides an indicative guide to how the TRIPS Agreement could and should be amended. The drafting of the exact scope of potential amendment provisions and articles, however, is left to be determined by future research.

experts in the field of human rights with a particular focus on the right to health, and open for broad consultation and debate.

5.2.2.1 Explicit Differential Treatment of Pharmaceutical Products in Comparison to Other Commodities

The revision of the TRIPS Agreement being proposed here, suggesting specific regulations for the patentability of pharmaceutical products, is based on a fundamental change to the patent section of the agreement, facilitating the differential treatment of pharmaceuticals by abolishing the requirement that patents shall be available without discrimination as to the field of technology. Distinguished from the IPT Project's proposed amendment to Article 27 TRIPS, it is submitted that the anti-discrimination principle as to the field of technology should not only be dropped, but that pharmaceutical products should be explicitly treated differently from patents in other fields of technology. In this regard, I suggest two possible approaches to facilitating the differential treatment of pharmaceutical patents. Firstly, Article 27 can be amended to explicitly require the differential treatment of pharmaceutical products and processes, with further specific regulations on pharmaceutical patents being implemented into a revised patent section of the TRIPS Agreement. Secondly, in a more radical approach, the patentability of pharmaceutical products may be entirely disconnected from the current patent section of TRIPS, adding a new section to Part II of the agreement that specifically focusses on the regulation of pharmaceutical patents.

The rationale behind the differential treatment of pharmaceutical patents is derived from the fact that pharmaceutical products exhibit distinct differences from other technological sectors, particularly with regard to their impacts on the health, life, and dignity of human beings. Life-saving medicines are fundamental to human wellbeing and thereby disparate from other commodities such as new smartphones which a consumer can freely choose not to purchase until the prices drop.¹⁴⁶ Not being able to promptly afford new medications, on the other hand, may be decisive for the death or survival of a patient. Furthermore, monopoly prices for ordinary products are more elastic than those of medicines, as consumers are likely to refrain from purchasing overpriced commodities, so that the price range of such products is limited by the

¹⁴⁶ Hunt P and others, *Neglected Diseases: A Human Rights Analysis* (WHO 2007) 13.

maximum amount consumers are willing to pay.¹⁴⁷ As elaborated in chapter 4.2.2, however, individuals burdened by diseases rely on medical treatment, with the result that patients commonly accept higher prices for medicines, meaning that monopolists on pharmaceutical markets exercise greater freedom regarding the increase of prices to unreasonable levels.

Consequently, it is submitted that the disparities between pharmaceutical products and other commodities confirm the urgent requirement that pharmaceutical patents are specifically regulated in an adequate manner, different from patents in other fields of technology. Notably, this requirement seems to be implicitly recognised by the Doha Declaration which provides specific measures for the protection of public health, rendering the differential treatment of health-related patents necessary.¹⁴⁸ In the long run, an amendment of Article 27 TRIPS therefore seems inevitable for balancing patent rights with public health concerns.

5.2.2.2 Revision of the Rights Conferred

Article 28 TRIPS provides patent holders with exclusive rights, enabling them to, inter alia, prevent third parties from using their patented inventions.¹⁴⁹ This provision entails the possibility that patent holders exert their rights to restrict the use of their products and processes by other researchers. Thus, to ensure that patents themselves do not create obstacles for adequate research activity, an amendment of Article 28 is required. This amendment needs to stipulate that the right to prevent others from using a patented invention shall not encompass uses which are necessary for conducting further research to improve upon an invention, or for developing new products based on patented processes or prior inventions. If such use leads to the development of new products, the implementation of a derivative right for the initial patent holders may be considered which grants them a reasonable share of new patents, proportionate to the contribution of the original patent to the new invention. This approach differs from the proposal of the IPT Project, which provides a limitation clause, exempting the use for

¹⁴⁷ Flynn S, Hollis A, and Palmedo M, 'An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries' (2009) 37 Journal of Law, Medicine & Ethics 184, 187.

¹⁴⁸ Correa CM, *Implications of the Doha Declaration on the Trips Agreement and Public Health* (WHO 2002) 42; IPT Project, 'Explanatory Memorandum' (n 116) 578-579.

¹⁴⁹ TRIPS Agreement (n 121) Article 28.

research purposes from patent protection in an amendment of Article 30 TRIPS that evokes semblance to a generalised exception.¹⁵⁰ An amendment to Article 28 TRIPS, on the other hand, can provide a specific definition of the term ‘use’ within the regulation itself, stipulating that the term shall never encompass uses for further research activities.

5.2.2.3 Implementation of Obligations of (Pharmaceutical) Patent Holders

In recognition that the objectives of the TRIPS Agreement affirm the existence of both rights and obligations, which, according to Article 7 TRIPS, must be balanced with each other,¹⁵¹ Part II of the TRIPS Agreement exhibits a distinct lack of any elaborate obligations of patent holders. While Article 28 TRIPS provides a clear definition of the rights conferred by patents, there is currently no similar provision addressing concomitant obligations. I therefore propose the implementation of an Article 28*bis*, titled ‘Obligations of Patent Holders’, which in particular shall stipulate explicit provisions establishing the obligations of pharmaceutical patent holders. Notably, clear rules are required which implement obligations towards the accessibility of medicines to facilitate that public health becomes a main concern of patent standards, rather than being side-lined to the exceptions, as discussed in chapter 4.2.3.¹⁵²

In this respect, it is suggested that a first obligation of pharmaceutical patent holders shall stipulate that patented medical products must be made available worldwide, without any unreasonable delay. To this end, it is paramount that the acts of withdrawing pharmaceutical products from a specific market, and/or refraining from introducing new medicines to a specific country as a retaliation for allegedly insufficient domestic patent protection standards or the use of compulsory licenses, as elaborated in chapter 2.4.3.7, shall be explicitly prohibited. A violation of this prohibition shall constitute a reason for the revocation of a patent. To add force to this obligation, and to ensure that required medications are available in all countries alike, the revocation should not only be applicable in a domestic context. Instead, a severe

¹⁵⁰ cf. IPT Project, ‘Proposed Amended Text’ (n 120) 493.

¹⁵¹ TRIPS Agreement (n 121) Article 7.

¹⁵² Cullet P, ‘Patents and Medicines: The Relationship between TRIPS and the Human Right to Health’ (2003) 79 International Affairs 139, 155.

breach of this obligation should facilitate considerations of a global revocation of the respective patent, as elaborated below in 5.2.2.6.

Additionally, following Guidelines 5 and 33 of Hunt's Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines, the realisation of the accessibility of medicines for all requires corporations to pay due regard to disadvantaged people and communities, and particularly to populations living in poverty, when implementing their pharmaceutical pricing policies.¹⁵³ In recognition of Guideline 34, pharmaceutical corporations should furthermore take particular account of the stage of a country's economic development.¹⁵⁴ Based on these principles, it is submitted that the TRIPS Agreement should entail an obligation for pharmaceutical patent holders to refrain from excessive pricing strategies, particularly where such strategies would induce prohibitive prices in low-income countries. As elaborated in chapter 4.2.2, it can be economically viable to charge higher drug prices in poor markets than in industrialised countries, as the profitability peaks in inelastic demand curves when the prices are set so high that they are only affordable to the richest ten percent of the population. While it may be impracticable to define clear upper limits of permissible prices, the current situation indicates the need for the introduction of a means to identify whether prices are so excessive that they amount to an abuse of a monopolistic market position. Such an abuse should then be defined as a reason for the revocation of the patent under Article 32 TRIPS.

Furthermore, the TRIPS Agreement should not merely prevent the abuse of patent rights, but rather oblige pharmaceutical corporations to take active steps towards realising the accessibility of their patented products. In this respect, pharmaceutical patent holders should be required to offer medicines in developing countries at cheaper prices than in industrialised nations. Currently, however, a differential pricing system is not feasible, as its facilitation requires further changes to the TRIPS Agreement, particularly to Article 6 addressing the exhaustion of IP rights, as elaborated in the next section. Similarly, corporations should be required to engage in meaningful research, especially with regard to tropical diseases that mainly affect poor populations. The introduction of such a responsibility, however, is not entirely unproblematic, as private corporations would seemingly be required to make private

¹⁵³ cf. Hunt P, 'Human Rights Guidelines for Pharmaceutical Companies' (n 81) Guidelines 5 and 33.

¹⁵⁴ *ibid* Guideline 34.

investments against their economic interests, for the fulfilment of a public function, as further elaborated below in 5.2.2.5.

Lastly, a revised TRIPS Agreement can theoretically elevate Hunt's Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines to a legally binding status, at least for patent holding corporations, by implementing an obligation for pharmaceutical patent holders to comply with the Guidelines. While such a move would provide a solution for the current voluntariness of the Guidelines, the specific responsibilities of pharmaceutical corporations would be relegated to an instrument outside the international patent system. Therefore, key obligations of pharmaceutical patent holders should nevertheless be explicitly implemented into the TRIPS Agreement. Only then could an additional reference to Hunt's Guidelines add a further level to the human rights responsibilities of pharmaceutical patent holders.

5.2.2.4 Facilitating Differential Pricing Strategies

A differential pricing strategy is based on the idea that the prices of medical products should be proportionate to the wealth or poverty level of the country where the medicine is sold.¹⁵⁵ In other words, differential pricing pays due regard to the actual economic and social differences between developing countries and industrialised nations.¹⁵⁶ The successful realisation of a differential pricing strategy requires that in developing countries, the pharmaceutical industry implements a low-price-high-volume marketing policy.¹⁵⁷ Differential pricing strategies for pharmaceutical products are thus commonly based on the Ramsey Pricing model. The theory behind Ramsey Pricing provides that the prices of medicines in each individual market shall at least be equal to their marginal production costs, while the prices in all markets combined need to lead to a revenue that additionally covers at least the relevant R&D costs, and further provides a reasonable profit.¹⁵⁸ By applying this model, the research-

¹⁵⁵ Bakhoun M, 'TRIPS, Patent Rights and Right to Health: "Price" or "Prize" for Better Access to Medicines?' (2009) Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series No. 10-07 <<https://ssrn.com/abstract=1619215>> accessed 24 February 2019, 30.

¹⁵⁶ *ibid* 35.

¹⁵⁷ Abbott FM and Reichman JH, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 JIEL 921, 982.

¹⁵⁸ For further discussion of the Ramsey Pricing model see: Bakhoun M (n 155) 36; Opderbeck DW, 'Patents, Essential Medicines, and the Innovation Game' (2005) 58 Vand. L. Rev. 501, 531.

based industry can recoup their R&D investments by keeping medicine prices in wealthy countries comparatively high, while the drug prices in low-income countries can be kept close their production costs to increase their accessibility for the poor.¹⁵⁹ This implies, however, that patients in industrialised countries have to accept high drug prices to maintain the required research incentives.¹⁶⁰

A substantial problem inherent to the differential pricing approach is that the pharmaceutical industry fears a dilution of drug prices in wealthy markets, as cheaper products may be parallel imported from developing countries, particularly when industrialised nations apply a system of international exhaustion.¹⁶¹ Notably, international exhaustion enables consumers to import cheaper products that were lawfully placed on markets in other countries.¹⁶² Therefore, the current exhaustion rule under Article 6 TRIPS, which enables domestic states to freely implement their preferred exhaustion regime, is insufficient for facilitating differential pricing strategies.¹⁶³ Consequently, it is submitted that in order to encourage, or even require pharmaceutical patent holders to adopt a differential pricing policy, Article 6 TRIPS needs to be revised accordingly.¹⁶⁴ It must be noted, however, that such a revision cannot simply mandate that all countries shall apply national exhaustion regimes, which are impossible to implement in regional trade areas¹⁶⁵ such as the EU.¹⁶⁶ It follows that any amendment to Article 6 TRIPS must rule out international exhaustion regimes, while at the same time retaining the possibility for regional unions to implement a regime of regional exhaustion. Otherwise, such a revision would inevitably lack the required support of the EU and other regional trade areas. As a result, differential pricing strategies cannot be facilitated within regional unions. This can raise particular issues in unions consisting of mid- and low-income countries,

¹⁵⁹ Bakhoun M (n 155) 36; Opderbeck DW (n 158) 531; Trouiller P and others, 'Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure' (2002) 359 *The Lancet* 2188, 2191.

¹⁶⁰ Bakhoun M (n 155) 36.

¹⁶¹ Abbott FM and Reichman JH (n 157) 971; Bakhoun M (n 155) 37; Opderbeck DW (n 158) 531.

¹⁶² Bakhoun M (n 155) 37.

¹⁶³ *ibid* 38.

¹⁶⁴ *ibid* 31.

¹⁶⁵ For an overview of exhaustion regimes, see chapter 2.4.2.2.

A system of national exhaustion cannot be applied in regional trade areas, such as the EU, as trade regions are based on the free flow of goods and services. A strictly national exhaustion regime, however, would enable patent holders to prevent the export of products that have been legally placed on a market, to the markets of other countries. This would then restrict the free flow of goods and services, thereby undermining the very purpose of regional trade areas.

¹⁶⁶ Opderbeck DW (n 158) 531.

where it must be expected that medicine prices are set at a level proportionate to the wealth of the mid-income countries. Ultimately, however, where an amendment to the TRIPS Agreement prevents the parallel importation of drugs from poor countries to wealthy markets, a differential pricing strategy can be implemented on an international level.¹⁶⁷

A further obstacle for the adoption of a differential pricing strategy is that the pharmaceutical industry may be exposed to reference pricing strategies utilised by wealthy countries, which negotiate for cheaper drug prices with reference to the prices charged in low-income countries.¹⁶⁸ This is a particular concern for the research-based industry, when, according to differential pricing policies, the prices charged in developing countries merely entail marginal profits.¹⁶⁹ It follows that if wealthy countries use developing country prices as benchmarks in price negotiations, the pharmaceutical industry loses its capability to recoup R&D costs.¹⁷⁰ Consequently, differential pricing strategies can only be feasible if industrialised nations refrain from referencing lower prices available to developing countries.¹⁷¹ A potential solution for this problem is suggested in the implementation of a ‘system of secret rebates’ which facilitates differential pricing by keeping the prices offered to individual countries secret, and therefore unavailable to foreign price negotiators.¹⁷² Such a system, however, may be susceptible to leaks which could be abused by industrialised country negotiators seeking to push for lower prices. I therefore propose that a meaningful solution should clearly define parameters in the very provisions proposed for the regulation of differential pricing strategies in the TRIPS Agreement, which explicitly prevent industrialised countries from utilising reference pricing as a means to lower medicine prices to developing country levels.

Lastly, it must be acknowledged, however, that differential pricing policies cannot provide a comprehensive solution for all the issues associated with the accessibility of medicines in developing countries. While differential pricing offers certain solutions

¹⁶⁷ cf. Bakhoun M (n 155) 38.

¹⁶⁸ Abbott FM and Reichman JH (n 157) 971; Bakhoun M (n 155) 37; Opderbeck DW (n 158) 532; Reichman JH, ‘Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options’ (2009) *Pharmaceutical Regulations* 247, 251.

¹⁶⁹ Reichman JH (n 168) 251.

¹⁷⁰ *ibid* 251.

¹⁷¹ Bakhoun M (n 155) 39.

¹⁷² Reichman JH (n 168) 251.

regarding the pricing of pharmaceutical products in developing countries, such a system is only feasible for medications that treat diseases which are prevalent in both low-income and high-income countries.¹⁷³ This is because differential pricing is based on the theory that by recouping R&D investments and realising reasonable profits in wealthy markets, a research incentive for new medications can be established, despite prices in developing countries being low. For neglected diseases, on the other hand, there are commonly no viable markets in industrialised countries, so that the necessary R&D investments cannot be recovered there, meaning that differential pricing does not offer incentives for the development of medicines for the poor.¹⁷⁴ Furthermore, even if medications for neglected diseases were developed, differential pricing strategies would not be applicable, as without the availability of wealthy markets, prices in developing countries would remain high. It can thus be concluded that differential pricing strategies offer solutions for the pricing problem of medicines in developing countries only for products with global markets, leaving the issues surrounding neglected diseases unresolved.¹⁷⁵

5.2.2.5 *Research Incentives for Neglected Diseases*

By and large, the scope of this thesis reveals that current international patent laws are insufficiently equipped for addressing the specific issues of medicines with minor demand on global markets. From this it can be concluded that a system which relies solely on market conditions for incentivising investments is inadequate for encouraging appropriate pharmaceutical research activities.¹⁷⁶ In further recognition of the adverse impacts of high drug prices on public health, it must be questioned whether the prospect of monopoly pricing is ultimately the most favourable way of incentivising pharmaceutical R&D.¹⁷⁷ As long as patents function as the primary research incentive, however, patent laws should provide clear regulations and specifications on the scope of appropriate research. In particular, benchmarks should

¹⁷³ Bakhoun M (n 155) 36.

¹⁷⁴ Opderbeck DW (n 158) 532; Trouiller P and others (n 159) 2191.

¹⁷⁵ Bakhoun M (n 155) 40.

¹⁷⁶ cf. Dreyfuss RC, 'Patents and Human Rights: Where is the Paradox?' in Grosheide W (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar Publishing 2010) 90.

¹⁷⁷ Henry D and Searles A, 'Chapter 9: Pharmaceutical Pricing Policy' in Management Sciences for Health, *MDS-3: Managing Access to Medicines and Health Technologies* (3rd edn, Management Sciences for Health 2012) 9.17.

be defined, ensuring that patent protection levels distinctly reflect the effort that goes into the development of a new pharmaceutical product. It is therefore proposed that patent protection should be proportionate to research expenses, meaning that incremental developments should not receive the same term of protection as ground-breaking research projects.¹⁷⁸

As patent protection nevertheless only provides incentives where there are profitable markets, the encouragement of research into neglected diseases appears to require a more radical approach, potentially by implementing clear responsibilities or obligations. It may be quite problematic, however, to propose the imposition of research obligations for the development of public goods on private corporations, particularly when concomitant investments expose corporations to the risk of incurring losses. The prevailing question would be, how to justify that some corporations are required to make private investments into the development of public goods, but not others?

At the same time, the granting of exclusive patent rights shall, in fact, stimulate research by enabling corporations to increase their profitability by charging higher prices. Such an incentive, however, is insufficient for satisfying some of the most urgent research needs. It may therefore be reasonable to suggest that the award of patent rights should be subjected to specific qualifications and requirements. Considering that high prices only provide sufficient incentives for the development of medicines with markets in wealthy countries, an obligation should be introduced, requiring patent holders to spend a certain amount of their monopoly profits on research into neglected diseases.¹⁷⁹ To be effective, it is crucial for such an obligation to be implemented on a global scale. An amendment to TRIPS that simply provides domestic governments with the option of implementing a provision that requires patent holders to conduct research into local diseases may discourage pharmaceutical corporations from placing new products on respective markets, particularly in developing countries and LDCs.¹⁸⁰ On balance, however, it must be acknowledged that such a solution is still not optimal for addressing the specific issues surrounding neglected diseases, and that more research is required to identify how the TRIPS

¹⁷⁸ See thereto: chapters 4.3.2.2, 4.3.2.3, and 4.3.5.

¹⁷⁹ Opderbeck DW (n 158) 551; Trouiller P and others (n 159) 2193.

¹⁸⁰ Opderbeck DW (n 158) 550-551.

Agreement can effectively ensure that the research-based pharmaceutical industry pays due regard to the needs of the poor.

Ultimately, one may need to accept that a patent system under which incentives for innovation are solely reliant on market forces may simply not be the optimal place for seeking solutions to the neglect of research into diseases for which there is no market. Notably, the private business sector which needs to be incentivised, is driven by economic interests, which by their nature do not cater for the needs of certain groups and populations, if the fulfilment of such needs is economically not viable.¹⁸¹ Applied in context, it can be observed that the development of new medical products entails substantial opportunity costs, so that drugs with minor profitability prospects do not provide economic incentives, irrespective of the strength of the available patent protection.¹⁸² In further recognition that the development of new medicines serves an essential public health function, it should not be left to the profit driven private business sector alone.¹⁸³ Instead, strong public commitments are required.

It is important to realise that the provision of market exclusivity under patent laws is not the only available option for incentivising pharmaceutical research.¹⁸⁴ On the contrary, governments can resort to non-market incentives, so-called push mechanisms, for example, by providing tax concessions based on investments rather than results; by subsidising research investments into neglected diseases; or by providing public grants for specific research projects.¹⁸⁵ Similarly, governments could make purchase commitments for medicines treating neglected diseases prior to their development, thereby mitigating the risks of non-viable markets.¹⁸⁶ In special consideration of neglected diseases, another approach which is suggested, is the establishment of a so-called ‘prize system’ according to which successful innovators can choose to receive a monetary reward instead of patent protection, subject to the

¹⁸¹ Ziegler AR and Boie B, ‘The Relationship between International Trade Law and International Human Rights Law’ in de Wet E and Vidmar J (eds), *Hierarchy in International Law: The Place of Human Rights* (OUP 2012) 287.

¹⁸² Opderbeck DW (n 158) 535 and 543.

¹⁸³ Sell SK, ‘TRIPS-Plus Free Trade Agreements and Access to Medicines’ (2007) 28 *Liverpool Law Review* 41, 70.

¹⁸⁴ Abbott FM, ‘Trade in Medicines’ in Smith R and others (eds), *Trade and Health: Towards Building a National Strategy* (WHO 2015) 126.

¹⁸⁵ cf. *ibid*; Henry D and Searles A (n 177) 9.17; Trouiller P and others (n 159) 2191; Outtersson K, ‘Disease-Based Limitations on Compulsory Licenses under Articles 31 and 31bis’ in Correa CM (ed), *Research Handbook on the Protection of Intellectual Property under WTO Rules: Intellectual Property in the WTO Volume I* (Edward Elgar Publishing 2010) 689.

¹⁸⁶ Abbott FM, ‘Trade in Medicines’ (184) 126.

actual contribution of an invention.¹⁸⁷ Such an approach not only provides a research incentive for neglected diseases, but furthermore ensures that newly developed medicines immediately enter the public domain.¹⁸⁸ When a prize system then runs parallel to a patent system, the patent system can be utilised to incentivise research into diseases with global markets, while the prize system can foster research investments into neglected diseases.¹⁸⁹ The remaining question, however, is who shall pay for the prizes offered? This crucial question applies equally to all subsidies offered as research incentives. For neglected diseases, Abbott suggests that subsidies should be internationally coordinated.¹⁹⁰ Ultimately, the successful creation and sustainability of a system of subsidies is heavily dependent on political sentiments.¹⁹¹ In the end, it must nevertheless be recognised ‘that governments are in the best position to provide and regulate essential public goods.’¹⁹²

5.2.2.6 Non-compliance as Reason for Revocation

The TRIPS Agreement only briefly, and arguably insufficiently, addresses options for the revocation and forfeiture of patent rights. In fact, the agreement refrains from providing any specific conditions or reasons which explicitly permit the revocation of a patent. In its current form, Article 32 TRIPS reads: ‘An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.’¹⁹³ It follows that the only regulation provided on this matter is a protection clause for patent holders against arbitrary expropriation. There are no distinct measures, however, for the protection of the public interest. In order to give force to the obligations of pharmaceutical patent holders proposed in this chapter, it is therefore crucial to amend Article 32 to implement an enforcement mechanism by rendering non-compliance with the proposed obligations a reason for the revocation of patents.

In particular, a revised Article 32 should explicitly prohibit the abuse of patent rights, by stipulating that any such abuses shall result in the revocation of the respective

¹⁸⁷ Bakhoun M (n 155) 42-43.

¹⁸⁸ Bakhoun M (n 155) 43.

¹⁸⁹ *ibid* 43 and 46.

¹⁹⁰ Abbott FM, ‘Trade in Medicines’ (184) 126.

¹⁹¹ cf. Opderbeck DW (n 158) 544.

¹⁹² Abbott FM and Reichman JH (n 157) 983.

¹⁹³ TRIPS Agreement (n 121) Article 32.

patents.¹⁹⁴ In this respect, the affordability of patented medicines can be established as a requirement for patentability by defining that excessive pricing of medicines shall constitute an abuse of monopoly powers. Similarly, where corporations arbitrarily refuse to place patented products on certain markets where medications are needed, an opportunity for revocation must be available to ensure that patients gain access to the required treatment. In this regard, it must be remembered that a number of developing countries and LDCs lack the capacity to produce generic medicines. A national revocation of patents may thus be insufficient for facilitating that the required medications reach all people in need. The revocation of patents for severe abuses of monopoly powers should therefore be internationally coordinated. While it may be too radical to suggest that a patent should then be globally revoked, a mechanism seems to be required which ensures that generics can be produced in countries with pharmaceutical production capacities for the export to countries where a patent has been revoked, without the need of going through the compulsory licensing system.

Ultimately, it is crucial that an amended TRIPS Agreement facilitates the enforcement¹⁹⁵ of the proposed obligations for pharmaceutical patent holders. In this respect, these obligations need to become an integral part of patent laws and non-compliance must be a reason for revocation. Article 32 TRIPS therefore needs to be revised to explicitly define the permissible grounds for revocation. This enumeration should be non-exhaustive to ensure that governments can adapt their patent laws to unforeseen circumstances in the future. A general problem with the enforcement of such obligations, however, is that it is reliant on the willingness of governments to implement the required domestic legislation. If a state refrains from implementing appropriate revocation mechanisms, there are currently no means under TRIPS which enable the general public to challenge the inactivity of governments, as the WTO Dispute Settlement Understanding (DSU) only concerns TRIPS disputes that are brought by a state against another state.¹⁹⁶ To ensure the effective protection of the

¹⁹⁴ cf. Beiter KD (n 111) 479.

¹⁹⁵ It must be noted here that the enforcement mechanisms for the proposed amendment only concern the domestic or regional enforcement of the newly proposed obligations of pharmaceutical patent holders. Further issues may arise in regard to WTO dispute settlement proceedings. An analysis of how the WTO DSU would most likely deal with conflicts arising under the proposed amendment, however, exceeds the scope of this thesis, and is therefore left to be determined by future research.

¹⁹⁶ WTO, 'Introduction to the WTO dispute settlement system' <https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c1s4p1_e.htm> accessed 28 May 2019.

public interest, a mechanism is thus required which enables the general public, or NGOs acting on behalf of the public interest, to challenge states that fail to adequately implement the proposed enforcement mechanisms.

5.2.2.7 Ceilings of Protection

Scrutinising the justification of the current international patent regime, chapter 4.2.3 identified that one of the main obstacles for the establishment of a balanced patent system is that the TRIPS Agreement, while providing a clear minimum of IP protection, refrains from defining appropriate maximum protection standards. Therefore, to ensure that patent protection is not raised to unreasonable levels, TRIPS should be revised to include clearly defined ceilings of protection. When considering the introduction of such ceilings, there are two potential ways by which upper limits can be established. Firstly, ceilings can be defined as limitations to the protection conferred by patents, as suggested by the IPT Project's proposed amendment of Article 30 TRIPS, elaborated earlier in this chapter.¹⁹⁷ Secondly, ceilings of protection can be established by implementing upper limits to which IP protection can extend, for example, by defining a distinct maximum patent period, applicable to both governments enacting domestic patent provisions and international FTAs establishing TRIPS-Plus patent standards. The second approach connects to the peculiarity of international IP laws which have historically only aspired to strengthening IP rights, leading to ever-increasing protection levels without sufficient attention to considerations of proportionality.¹⁹⁸

Unfortunately, this trend is currently permissible under TRIPS, as Article 1(1) explicitly enables states to grant stronger IP protection than that provided for by the minimum standards defined in the agreement.¹⁹⁹ Article 1(1) qualifies this permission by requiring that higher protection levels shall 'not contravene the provisions of this Agreement.'²⁰⁰ Pragmatic experience, however, indicates that this qualification leaves too much leeway, as it can be observed that TRIPS-Plus FTAs frequently impose

¹⁹⁷ cf. Kur A and Grosse Ruse-Khan H, 'Enough is enough – the notion of binding ceilings in international intellectual property protection' in Kur A and Levin M (eds), *Intellectual Property Rights in a Fair World Trade System: Proposals for Reform of TRIPS* (Edward Elgar 2011) 380.

¹⁹⁸ *ibid* 361.

¹⁹⁹ TRIPS Agreement (n 121) Article 1(1).

²⁰⁰ *ibid*.

unfavourable IP standards on developing countries, contravening their public interests. It is therefore suggested that a clear definition of distinct maximum standards can provide a better safeguard against the introduction of excessive patent protection.

It must be acknowledged here that the suggested limitations in the amendment to Article 30 TRIPS proposed by the IPT Project, indicate a suitable approach to providing ceiling rules by adopting mandatory exceptions from patent protection in order to enable governments to establish an adequate balance between private and public interests.²⁰¹ As the first approach to introducing adequate ceilings of protection is thus appropriately addressed by prior scholarship, the following section of this chapter will elaborate on the second approach, with a particular focus on the introduction of maximum protection periods.

When proposing the introduction of ceiling rules regarding patent periods, it may be suggested that the current 20-year term of protection seems to be quite excessive for pharmaceutical products, especially in respect of the adverse impacts of monopolistic market positions on the affordability of medicines. In consideration of the global acceptance of this minimum protection term, however, it seems that the international community regards 20 years as the appropriate duration for incentivising and rewarding successful R&D efforts. Therefore, any attempt at lowering the minimum protection period is expected to encounter considerable opposition, with meagre prospects of success. In return, accepting that this term is sufficiently appropriate for incentivising R&D, it can be suggested that patent protection should not generally be extendable beyond 20 years. Consequently, any extension to the minimum patent period should be based on reasonable grounds, for example to compensate for administrative delays or marketing approval times. It is therefore proposed that the TRIPS Agreement should be revised to reflect that the minimum patent protection period of 20 years shall likewise constitute the generally permissible maximum. To protect the public interest, patent term extensions to compensate for administrative delays should be an exception to the general rule, and not the rule itself. While dissenting opinions may potentially suggest that the maximum duration should be longer than the minimum term, such an approach seems inadequate, as it entails the risk that industry lobbyists seek to push governments to always grant the maximum

²⁰¹ cf. Kur A and Grosse Ruse-Khan H (n 197) 380.

patent term, so that the ceiling of protection would effectively become the new minimum standard.

Furthermore, I suggest that the TRIPS Agreement should directly address secondary patents for new uses and new dosages of existing medications, which is currently not possible under TRIPS itself, as Article 27 explicitly requires patentable innovation to be new and to involve an inventive step.²⁰² Article 1(1), on the other hand, permits the implementation of more extensive protection.²⁰³ As this seemingly enables TRIPS-Plus FTAs to frequently require the granting of secondary patents, as elaborated in chapter 2.5.1.1, the TRIPS Agreement should be revised and adapted to this new situation. In particular, it is proposed that TRIPS should stipulate that secondary patents on prior existing products shall not qualify for the same 20-year minimum protection period as regular innovations. Instead, the term of protection should be proportionate to the effort required to detect a new use or new dosage. It follows that the protection of secondary patents should regularly be shorter than the protection granted to radically new innovations. To establish a proportionate level of protection, corporations seeking secondary patents should be required to disclose the research investments made towards the discovery of a new use or new dosage. The appropriate protection term can then be calculated based on the specific costs involved. As such a system may be susceptible to abuse, clear guidelines for the definition of eligible costs are required to prevent corporations from submitting strategic calculations indicating higher than actual investments.

From a public health point of view, it is submitted that for first patents on new innovations, a similar approach of proportioning the level of protection to the contribution of an invention or the research efforts involved would be more suitable for the establishment of an adequate balance between private and public interests. In particular, it can be questioned why incremental innovations should receive the same protection term as high-risk ground-breaking research projects. It must be re-acknowledged, however, that an attempt at lowering the 20-year minimum protection term for an initial patent is likely to be regarded as too radical with little chance of

²⁰² TRIPS Agreement (n 121) Article 27(1).

²⁰³ *ibid* Article 1(1).

success, and therefore currently not a sensible approach to proposing an amendment of the TRIPS patent regime.

Ultimately, to prevent patent protection being raised to inappropriate levels, it is fundamental to at least define clear maximum protection standards, including a distinct maximum protection term. Irrespective of the chosen term, introducing ceilings of protection for patent rights requires amendments to both Article 1 and Article 33 TRIPS. First, to facilitate the introduction of and adherence to general maximum protection standards, the wording of Article 1 TRIPS needs to be revised so that the allowance of more extensive protection is explicitly conditioned to defined maxima provided by the specific IP sections in Part II of the agreement. Second, an amendment to Article 33 TRIPS needs to define an explicit maximum protection term, and should further provide that the minimum protection period of 20 years is not applicable to secondary patents. Lastly, in recognition that the provision of a maximum protection term which deviates from the minimum patent period entails the risk that such a maximum is turned into the new minimum standard, the TRIPS Agreement should explicitly stipulate that any extension beyond minimum protection terms must be appropriately based on considerations of proportionality.

5.2.2.8 Introducing Clear Human Rights References to the TRIPS Agreement

At the present time, it can be observed that while explicitly addressing the importance of public health, both the TRIPS Agreement and the Doha Declaration refrain from the adoption of human rights language or making direct references to international human rights law, as discussed in chapter 3.1.3.2.²⁰⁴ In regard to the fundamental importance of human rights, and the considerable lack of a distinct hierarchy between trade law and human rights law on an international level, it is proposed that a revision of the TRIPS Agreement should provide an explicit reference to the validity of human rights

²⁰⁴ Abbott FM, 'The "Rule of Reason" and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPS' in Cottier T, Pauwelyn J, and Bonanomi EB (eds), *Human Rights and International Trade* (OUP 2005) 283; de Feyter K, *Human Rights: Social Justice in the Age of the Market* (Zed Books 2005) 181.

Similarly, the Doha Declaration explicitly recognises the importance of public health, without making any direct references to the human right to health. See thereto: World Trade Organization (WTO), 'Doha Declaration on the TRIPS Agreement and Public Health: Ministerial Declaration of 14 November 2001' (20 November 2001) WTO Doc WT/MIN(01)/DEC/2 [Doha Declaration].

standards. Such a reference should be drafted in a similar language as the current acknowledgement of the validity of the Paris Convention and the Berne Convention in Article 2(2) TRIPS. A newly adopted Article 2(3) could thus read:

*Nothing in this Agreement shall derogate from the existing human rights obligations of Members under the International Bill of Rights.*²⁰⁵

The Bill of Rights should then be defined as at least encompassing the UDHR, the ICESCR, and the ICCPR, although other human rights treaties and conventions should be regarded as well.

The proposed implementation of a human rights reference in Article 2(3) TRIPS can effectively introduce a binding conflict clause, by establishing a clear link between trade law and human rights.²⁰⁶ Thereby, human rights can be placed at the core of the TRIPS Agreement, providing overarching obligations, rather than mere exceptions to the general rule.²⁰⁷ As a result, external human rights provisions can act as valid limitations to the IP rights of TRIPS, and thus contribute to the establishment of an appropriate balance of private and public interests, ensuring that private rights do not hinder the realisation of public health.²⁰⁸ In other words, human rights standards themselves could become mandatory ceilings of IP protection. Furthermore, by establishing that the TRIPS Agreement shall not contravene human rights norms, governments would be permitted to adopt measures inconsistent with the TRIPS Agreement for the protection of the right to health.²⁰⁹

5.2.2.9 Protection of Undisclosed Information

Besides the protection of pharmaceutical patents, the protection of undisclosed information submitted for the marketing approval of new medicines under Article 39(3) TRIPS can also create severe obstacles for the realisation of the right to health,

²⁰⁵ See for language reference: TRIPS Agreement (n 121) Article 2(2).

²⁰⁶ cf. United Nations Economic and Social Council (ECOSOC), 'The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights' (27 June 2001) Un Doc E/CN.4/Sub.2/2001/13, para 68.

²⁰⁷ Beiter KD (n 111) 479.

²⁰⁸ Kur A and Grosse Ruse-Khan H (n 197) 398.

²⁰⁹ Abbott FM, 'WTO TRIPS Agreement and its Implications for Access to Medicines in Developing Countries' (2002) United Kingdom Commission on Intellectual Property Rights, Study Paper 2a/2002, 3 <<https://ssrn.com/abstract=1924420>> accessed 11 October 2018.

as elaborated in chapter 2.4.4. Therefore, amendments to the patent section of the TRIPS Agreement, aimed at establishing an improved balance between private and public interests with particular respect to human health, should furthermore consider revisions to Article 39 TRIPS. In particular, the protection of undisclosed information should not create obstacles for further research aimed at improving an invention, or the marketing approval of generic drugs entering the market after a patent expires. In similar fashion to the suggested amendments to the regulation of pharmaceutical patents, it is submitted that the protection of undisclosed information should not simply side-line public health to an exception clause, but that a revised Article 39 should explicitly provide safeguards for its realisation.

5.2.3 Concluding remarks

In the final analysis, the preceding sections of this chapter can be summarised to provide an answer to Research Question 5:

Can responsibilities of pharmaceutical patent holders towards the realisation of the right to health be implemented into the TRIPS Agreement, in order to establish a balance between private interests and public health, thereby enhancing the justification of the international patent regime?

As identified in chapter 4, the justification of the international patent regime is decisively dependant on the establishment of an adequate balance between private and public interests, which in turn is dependent on the balancing of the rights and obligations of IP rights holders. This is of particular concern in respect to the right to health, as the provision of pharmaceutical patent protection creates severe obstacles for the realisation of public health. Therefore, by introducing enforceable responsibilities of the pharmaceutical industry, an amendment of the TRIPS Agreement can provide the required balance of the rights and obligations of patent holders. This can then lead to the establishment of an adequate balance between IP rights and public health concerns, and a stronger justification of the international patent regime.

In this regard, I have argued in this chapter that it is the very patentability of pharmaceutical products itself which provides the opportunity for implementing the

responsibilities of pharmaceutical patent holders as a direct obligation into international IP laws. This is inherently connected to the circumstance that pharmaceutical corporations seek the protection of their inventions and research investments, as patents are a valuable asset to research-based industries. The granting of exclusive rights can, and should thus be subjected to concomitant obligations. For the regulation of specific obligations of pharmaceutical patent holders, and specific conditions to the patentability of pharmaceuticals more generally, it is crucial that Article 27 TRIPS is amended to facilitate the differential treatment of patents according to the field of technology. Then, obligations of pharmaceutical patent holders can be introduced by a newly implemented Article 28*bis*. The adherence to these obligations should furthermore be defined as a requirement for the patentability of pharmaceutical products. In particular, the obligations should require pharmaceutical patent holders to pay due regard to marginalised and vulnerable groups in their pricing policies, especially with regard to poverty levels in developing countries. To provide an enforcement mechanism, both the non-compliance with obligations as well as the abuse of monopolistic market positions should be explicitly defined as reasons for the revocation of patents. To furthermore prevent TRIPS-Plus FTAs from corrupting the newly established balance, ceilings of protection are required which, on the one hand, should provide distinct limitations to the scope of protection that is provided by patent rights, and, on the other hand, should clearly define a maximum protection period. Lastly, it is submitted that the best results in establishing an appropriate balance between private IP rights and public right to health concerns may be achieved by implementing a direct human rights reference into the general provisions of the TRIPS Agreement.

In general, there are two possible approaches suggested for the implementation of an amendment to the patent provisions of TRIPS in regard to pharmaceutical products. For the most part, the preceding proposals have focussed on the first approach, which aims to regulate pharmaceutical patents differently from patents on regular goods, by adopting specific provisions in added paragraphs and articles within the current patent section of TRIPS. The second approach, on the other hand, proposes that pharmaceutical patents should be completely disconnected from the current patent section. A new section should then be introduced to Part II of the TRIPS Agreement, which specifically regulates pharmaceutical patents with all their nuances and

intricacies. While this would ultimately be the preferred approach, it has to be recognised that this proposal is rather radical, and thus likely to face strong opposition and severe obstacles in international negotiations. It is therefore concluded that at the current time, the first approach seems to be the sensible way of proposing an amendment to the patentability of pharmaceutical products, as it has the greatest chance of successfully establishing the required balance between IP rights and public health.

Conclusion

As outlined in the Introduction to this thesis, almost two billion people around the globe lack adequate access to medical products.¹ It is estimated that ten million lives are lost each year due to the insufficient accessibility of life-saving medicines.² While it is acknowledged that a variety of reasons contribute to this inaccessibility, it is generally accepted that the prices of medicines, which are predominantly determined by the availability of pharmaceutical patent rights, are one of the main determinants of whether people living poverty can afford medical treatment.³

In light of this situation, and with particular regard to the detrimental impacts brought about by the international harmonisation of IP laws, which introduced the global patentability of pharmaceutical products, the main objective of this thesis has been the identification of the currently insufficiently defined responsibilities of pharmaceutical patent holders towards the right to health. In considering this, this thesis aimed to indicate potential improvements of the international patent regime, which could enhance the balance between the provision of private exclusive rights and the societal interest in public health. Before such improvements to the patent system could be proposed, however, it was important to elaborate on the shortcomings of the current patent regime, and its normative conflicts with human rights law. In this regard, Part I of this thesis provided an overview of the relevant legal framework, focussing on the right to health under international human rights law, and international patent laws

¹ Forman L, 'From TRIPS-Plus to Rights Plus? Exploring Right to Health Impact Assessment of Trade-Related Intellectual Property Rights through the Thai Experience' (2012) 7 AJWH 347, 350; Hunt P and others, *Neglected Diseases: A Human Rights Analysis* (WHO 2007) 33; Khosla R and Hunt P, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines: The Sexual and Reproductive Health Context* (University of Essex, 2008) 2; Lee JY and Hunt P, 'Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines' (2012) 40 J.L. Med. & Ethics 220, 220.

² Khosla R and Hunt P (n 1) 2; Lee JY and Hunt P (n 1) 220; Sellin J, *Access to Medicines: The Interface between Patents and Human Rights. Does one size fit all?* (Intersentia 2014) 21.

³ Hunt P and others, *Neglected Diseases* (n 1) 33; Forman L, 'From TRIPS-Plus to Rights Plus?' (n 1) 350; Forman L, 'Trade Rules, Intellectual Property, and the Right to Health' (2007) 21 Ethics & International Affairs 337, 339.

established by the TRIPS Agreement, and successive TRIPS-Plus free trade agreements (FTAs).

First, chapter 1 outlined the normative scope of the right to health under international human rights law with a particular focus on Article 12 ICESCR, which I regard as the most comprehensive affirmation of the right to health in that the covenant has an almost global reach, and is legally binding on its 161 state parties. The analysis of the right to health, *inter alia*, establishes that the accessibility of medicines constitutes a human right, as the highest attainable standard of health is only attainable when all people have sufficient access to affordable medical treatment. Furthermore, chapter 1 addressed the interrelation of human rights, indicating that health is an indispensable precondition for the realisation of other human rights, such as the rights to life and development. In brief, additionally to having the main obligation of realising and protecting the right to health in a domestic context, states are required to pay due regard to the right to health, both within their jurisdiction and in other countries, when entering into international agreements, such as TRIPS or TRIPS-Plus agreements. Lastly, while chapter 1 reaffirmed that states are the main duty bearers under international human rights law, non-state actors, such as the private business sector, have responsibilities towards the right to health, too. These responsibilities, however, are not sufficiently defined, and therefore unclear.

Successively, chapter 2 provided an overview of the current international patent regime, globally harmonised by the WTO TRIPS Agreement, and indicated its negative impacts on the accessibility of medicines. After briefly introducing the evolution of patent rights, this analysis examined the scope of the TRIPS Agreement's patent regulations, elaborating how the non-discrimination requirement as to the field of technology led to the global introduction of pharmaceutical patentability, and that the harmonised 20-year minimum protection term prolonged patent periods in a number of WTO member states. Furthermore, the analysis elaborated that the TRIPS Agreement's mere provision of minimum protection standards led to the introduction of so-called TRIPS-Plus agreements, which further strengthen IP protection levels. In particular, TRIPS-Plus agreements tend to relax patentability requirements, and restrict the use of the flexibilities and exceptions provided by the TRIPS agreement, thereby aggravating the problems created by pharmaceutical patent rights.

After providing an overview of the relevant legal framework in Part I, Part II of this thesis analysed the justification of the current international patent regime, and proposed improvements to the system, so that private patent rights can be adequately balanced with human rights objectives and the societal interest in public health. Before addressing the justification of the patent regime, however, it was important to establish the parameters against which the justification can be scrutinised. To this end, chapter 3 elaborated on whether there exists a legal hierarchy between the right to health and IP rights, or whether non-legal considerations may suggest the legitimacy of prioritising one above the other. In this regard, the first part of chapter 3 addressed Research Question 1:

What is the relationship between international human rights law and international IP/trade law?

In essence, the analysis found that under international law different treaty regimes are functionally detached, and therefore act independently from each other. It follows that currently there exists no hierarchical structure between the right to health and IP rights under international law. The comparatively strong enforcement mechanisms provided by international trade law, however, seem to lead to a factual prioritisation of trade concerns, jeopardising the adequate realisation of human rights.

In regard to the non-existing legal hierarchy, the second part of chapter 3 addressed Research Question 2:

Are there valid moral principles that can be utilised to justify the prioritisation of the right to health over contradictory provisions of international trade law and patent law?

This analysis elaborated on the concept of morality, focussing in particular on human dignity and human agency. Based on Gewirth's Principle of Generic Consistency (PGC), it is established that all human agents have equal rights to the generic needs necessary for their agency, i.e. the rights to freedom and well-being. Furthermore, Gewirth establishes a needs-based hierarchy, which prioritises those needs that are most essential for the realisation and protection of human life and well-being. By applying this needs-based hierarchy to the concept of human dignity, recognised as the foundation of human rights law, the PGC can be utilised to justify the prioritisation of

human rights that are fundamental for the realisation of human dignity over less-essential rights. Consequently, this thesis scrutinised the justification of the international patent regime, *inter alia*, against its compliance with the right to health.

In this respect, chapter 4 explored Research Question 3:

Recognising the importance of the right to health and access to medicines for human life in dignity, is the current international patent regime (under TRIPS and TRIPS-Plus) justified when the protection of private interests directly impacts on the affordability of medicines and public health?

The answer to this question was derived from two Sub-Questions. First, Sub-Question 3.1 asked:

Do the aims and purposes of patents justify a short-term restriction of the accessibility of medicines?

This analysis outlined the objectives and purposes of the international patent regime, which should, *inter alia*, provide enhanced research incentives, and, in the field of pharmaceutical patents, ultimately lead to the development of new medical products. In recognition of the crucial importance of the future availability of new medicines for the realisation of the right to health, the analysis raised the controversy of whether the availability of new medicines can justify a restriction of the accessibility of available medications for persons in need of treatment now. This controversy cannot be conclusively answered, as this would require the determination of whether current patients, or future patients are of higher importance, which conflicts with the basic human rights principle that all human beings are equal. It is suggested, however, that for a short-term restriction of the accessibility of medicines to be at all justifiable, pharmaceutical patent rights would need to adequately and completely fulfil their aims and purposes.

In this regard, the second part of chapter 4 addressed Sub-Question 3.2:

Do patents on pharmaceutical products actually fulfil their purposes and objectives?

In brief, the analysis indicated that patent rights are not capable of adequately fulfilling their purposes. It was observed that patents do not sufficiently incentivise the

development of radically new products, as particularly the relaxation of patentability requirements seems to incentivise research into low-risk marginal improvements. Similarly, patents fail to provide adequate incentives for conducting research into so-called neglected diseases, as medications for such conditions offer no viable markets. As the value of patent rights, however, is dependent on the existence of profitable markets, patents are by nature incapable of providing incentives for the development of medications for conditions that predominantly affect the poor. As patents thus fail in realising the sufficient availability of new medicines, the restriction of the accessibility of available medications cannot be regarded as justified. Consequently, Research Question 3 is negated, concluding that the current international patent regime is not justified. In particular, it is suggested that the current patent regime fails to provide adequate counter-balance mechanisms for the excessive rights provided to patent owners. This was considered to be directly attributable to the lack of a definition of distinct responsibilities or obligations of patent holders which could balance the private rights with public interests.

Recognising that some of the most detrimental impacts resulting from the patentability of pharmaceutical products can be averted by introducing responsibilities of pharmaceutical patent holders towards human rights, chapter 5 addressed the main objective of this thesis; the identification and implementation of responsibilities of the pharmaceutical industry towards the right to health. To this end, the first part of this chapter scrutinised existing approaches to the identification of corporate human rights responsibilities, which are traditionally based on the concept of corporate social responsibility (CSR). This analysis focussed in particular on international development goals and human rights guidelines for corporations, identifying their biggest flaw in the fact that these frameworks constitute non-binding soft law instruments. This issue was then addressed by Research Question 4:

Why is the corporate social responsibility approach of identifying the human rights responsibilities of the private business sector in non-binding international soft law instruments, insufficient for adequately regulating the pharmaceutical industry's conduct towards the right to health?

In essence, it was submitted that the implications of the right to health on the lives and livelihood of human beings are of such magnitude that the adherence to responsibilities for its respect and protection must not simply be regarded as a voluntary option.

Furthermore, the historic evidence suggests that leaving the realisation of the right to health to the goodwill of the pharmaceutical industry is insufficient, particularly when considering that the realisation of the accessibility of medicines directly impairs the revenues of profit driven corporations. In this regard, the second part of chapter 5 addressed this thesis's determinative Research Question 5:

Can responsibilities of pharmaceutical patent holders towards the realisation of the right to health be implemented into the TRIPS Agreement in order to establish a balance between private interests and public health, thereby enhancing the justification of the international patent regime?

The analysis suggested that the very patentability of pharmaceutical products itself provides a unique opportunity for implementing enforceable responsibilities of pharmaceutical patent holders as direct obligations under international IP laws. This opportunity arises from the fact that patents are valuable assets for research-based corporations which seek the protection of their R&D investments. Consequently, by revising the TRIPS Agreement, the granting of exclusive rights can be subjected to concomitant obligations. In this consideration, chapter 5 proposed a number of amendments to TRIPS. First, Article 27 could be revised to facilitate the differential treatment of pharmaceutical products, which significantly differ from ordinary commodities. Second, this thesis proposed the introduction of distinct obligations for pharmaceutical patent holders to ensure that patent rights do not interfere with the enjoyment of human rights. To further ensure the enforcement of these obligations, I proposed the introduction of clearly defined reasons for the revocation of patents, which should explicitly include the non-adherence to obligations as well as the abuse of exclusive market positions. Eventually, the introduction of distinct obligations would counterbalance the extensive rights granted by TRIPS, thereby harmonising the protection of private and public interests, and safeguarding that human rights concerns are duly regarded.

By applying Gewirth's Principle of Generic Consistency and the needs-based hierarchy to the concept of human dignity, in this thesis I have argued for a distinct moral rationale for suggesting the legitimacy of prioritising the human rights to health and life, over conflicting private patent rights under international trade law. This prioritisation then provided a clear foundation, enabling me to analyse the justification of the international patent regime from a right to health perspective. By further

accounting for the objectives and purposes of patent rights, I was able to strengthen the claim that the current international patent regime is not justified, either from a human rights perspective, or within itself. Scrutinising the results of this analysis, I particularly identified that the lack of distinct legal responsibilities of patent holders disregards the requirement of TRIPS to establish an adequate balance, both of rights and obligations under the agreement, and between private and public interests. I thereby reaffirmed the existence of an ongoing urgent requirement to introduce distinct responsibilities of pharmaceutical patent holders towards the realisation of the right to health.

Successively, after indicating that while existing approaches to implementing corporate responsibilities and mitigating the detrimental impacts of international patent laws are reasonable, and positive steps in the right direction, I suggested that the urgency of the current situation, which directly negatively impacts on the enjoyment of human life in dignity, requires a stronger approach. In addition to considering different concepts for addressing the known issues arising from the international patent regime throughout my research, the originality of this thesis lies particularly in adopting a non-conventional approach to addressing the specific challenges of pharmaceutical patentability, in that I explored the unique opportunity offered by pharmaceutical patent rights themselves, to regulate the activity of pharmaceutical patent holders. I therefore proposed an amendment to the patent section of TRIPS, diverging from the often-suggested general amendments to patent standards, as for example proposed by the IPT Project. Instead, I elaborated on the opportunity to specifically regulate pharmaceutical patents differently from patents on commodities in other fields of technology, proposing a patent system tailored to, and suitable for the specific requirements of pharmaceutical products. Acknowledging the distinct opportunity offered by pharmaceutical patent rights, I have taken a novel approach in that I suggested that patent laws should not only provide rights to pharmaceutical patent holders, but further implement distinct obligations, which, in accordance with Article 7 TRIPS, could then lead to an adequate balance of rights and obligations, paying due regard to the wider societal interest in health. To ensure the efficacy of these obligations, I further suggested that the obligations should become patentability criteria, so that the non-adherence to these obligations can be implemented as a ground for the revocation of a patent. While, because of the

constraints and limitations of this research, this thesis does not provide conclusive solutions to all issues created by pharmaceutical patentability, for example with regard to the encouragement of research into neglected diseases, my proposal offers a non-conventional approach away from identifying soft law responsibilities, towards implementing distinct enforceable legal obligations. My suggestions can thus offer a new perspective for future research and debates on these issues.

In particular, the findings of this thesis could, *inter alia*, feed into current discussions at UN level, including future work conducted under the recommendations provided by the final report of the United Nations Secretary-General's High-Level Panel on Access to medicines (hereinafter: 'the High-Level Panel').⁴ Despite having developed the scientific knowledge to make exceptional advances in the development of medicines, major parts of the world's population still lack adequate access to medical treatment. In this regard, and in particular recognition of SDG 3 which aims to promote the healthy lives and well-being of all people, then UN Secretary-General Ban Ki-moon established the High-Level Panel in 2015, with the task of reviewing the current incoherence between the rights of innovators under trade rules, and international human rights law.⁵ Under its mandate, the High-Level Panel addressed a variety of issues, including, among others, the interrelation between IP rights and access to health technologies,⁶ and incentives for the development of new health technologies, including medicines for neglected tropical diseases.⁷ While a detailed analysis of the High-Level Panel Report is not encompassed by scope of this thesis, it can be generally observed that the recommendations of the panel are mainly aimed at better utilising or improving existing tools, rather than changing the scope of current international legal norms, for example by suggesting that WTO members make full use of the TRIPS flexibilities, and by suggesting that governments shall refrain from pressuring other countries to neglect their right of using these flexibilities.⁸ Additionally, however, the High-Level Panel suggests the creation of 'an inter-agency taskforce on health technology innovation and access' with the purpose of overseeing the implementation

⁴ United Nations, 'United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies' (2016)
<<http://www.unsgaccessmeds.org/final-report>> accessed 21 September 2019.

⁵ *ibid* 3, 7, 12.

⁶ *ibid* 21-28.

⁷ *ibid* 29-32.

⁸ *ibid* 9.

of the High-Level Panel's recommendations, as well as 'increasing coherence among United Nations entities and relevant multilateral organizations like the WTO.'⁹ The report thus indicates the importance of paying continued attention to the issues arising between private IP rights the public interest in accessible health care, in order to find a sustainable long-term solution to these problems. To this end, the findings and suggestions of this thesis can provide an additional perspective to future debates on how to implement a balanced patent regime to safeguard the accessibility of medicines for everyone. Depending on political will, the indicative proposed amendment can then be utilised as a guide, supporting developing countries in future trade negotiations, when seeking to implement appropriately balanced patent standards.

Ultimately, this thesis concludes with the acknowledgement of the fundamental and indispensable importance of those human rights that realise and protect human life in dignity.

To deny any person their human rights is to challenge their very humanity.

– Nelson Mandela¹⁰

In respect to Mandela's words, it is thus submitted that private exclusive rights which directly impair the enjoyment of fundamental human rights cannot be justified. Consequently, in this thesis I have argued for the urgent necessity of amending the international patent regime in order to bring patent rights into accord with human rights demands. Focussing on the specific issues concerning the patentability of pharmaceuticals and the right to health, this thesis elaborates how the international patent regime can be amended, and what amendments are urgently required. The findings of this thesis lay the foundation for future research to draft the exact scope of a TRIPS amendment proposal, and can thereby feed into international debates on patents and human rights.

⁹ *ibid* 10.

¹⁰ New York Times, 'The Mandel Visit; Excerpts from Mandela Speech to Joint Meeting of Congress' *New York Times* (New York, 27 June 1990) <<https://www.nytimes.com/1990/06/27/world/the-mandel-visit-excerpts-from-mandela-speech-to-joint-meeting-of-congress.html>> accessed 17 May 2019.

Appendix

The Trans-Pacific Partnership Agreement and Its Threats to the Affordability of Medical Products in Developing Countries

Marc Stuhldreier

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Introduction

The Trans-Pacific Partnership Agreement (TPP) is a long-awaited and ambitious agreement which implements high standards for global trade. It was concluded in early October, 2015, and signed on 4 February 2016 following 6 years of negotiation. There are currently 12 nations from the Asia-Pacific region party to the treaty.¹ It is estimated that this region is the world's fastest growing market, predicted to have a middle class of about 3.2 billion people by 2030.² The aim of the agreement is to enhance trade and investment between the nations by resolving legal, political, and trade issues, including the protection of intellectual property (IP) rights.³ However, the introduction of the TPP should not be construed as an unmitigated success. There are concerns in relation

¹ These are Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States of America, and Vietnam <<https://ustr.gov/tpp/#what-is-tpp>> accessed 15 February 2016.

² United States Trade Representative, 'The TPP Intellectual Property Chapter Summary' (2015) <<https://ustr.gov/sites/default/files/TPP-Chapter-Summary-Intellectual-Property.pdf>> accessed 28 January 2016, 8.

³ Pike G, 'The Trans-Pacific Partnership and Intellectual Property' (2015) 32 Information Today 13.

to the disproportionate impact it will have on countries at various stages of development, as well as different sections in society.⁴

The TPP acknowledges the benefits which a high standard of protection for IP rights has for the promotion and development of pharmaceuticals. However, it has been subject to criticism for allowing multi-national corporations, in particular, the pharmaceutical industry,⁵ to exercise considerable influence over the drafting process.⁶ This involvement was criticised for promoting economic aims and maximisation of profits over public health interests in having affordable medicines, which are of particular importance for developing countries.

The IP section of the TPP significantly changes the current international patent regime by introducing increased data exclusivity provisions, creating the possibility of ‘evergreening’ patents due to the patentability of new uses of known products, and by increasing IP protection terms for office delays in granting patents and marketing approval.⁷ The TPP has therefore been accused of depriving people of adequate treatments by delaying generic competition in the pharmaceutical sector. This Agreement is likely to be unfavourable to those with serious health conditions who cannot afford adequate treatment.⁸ Several Non-Governmental Organisations (NGOs) have therefore warned that the agreement threatens the lives of millions of human beings.⁹ This view is supported by Médecins Sans Frontières which argues that increased patent provisions keep lifesaving treatment out of reach for large parts of the population of developing countries.¹⁰

⁴ See, for example: Ruckert A, Schram A and Labonté R, ‘The Trans-Pacific Partnership Agreement: Trading away our health?’ (2015) 106 Canadian Journal of Public Health 249.

⁵ Gleeson D and others, ‘How the Transnational Pharmaceutical Industry Pursues its Interests Through International Trade and Investment Agreements: A Case Study of the Trans Pacific Partnership’ in De Jonge and Tomasic (eds), *Handbook of Research on Transnational Corporations* (Edward Elgar Publishing Ltd., Forthcoming) 9 <<http://ssrn.com/abstract=2668576>> accessed 8 January 2016.

⁶ Beard M, ‘Trans-Pacific Partnership Agreement and the public health’ (2015) 128 The New Zealand Medical Journal (Online) 41, 41 <<https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2015/vol-128-no-1415/6550>> accessed 27 May 2019.

⁷ Ruckert A, Schram A, and Labonté R (n 4) 250.

⁸ McCall C, ‘Trans-Pacific trade pact triggers fears over drug prices’ (2015) 385 The Lancet 2450, 2450.

⁹ Kapczynski A, ‘The Trans-Pacific Partnership – Is It Bad for Your Health?’ (2015) 373 The New England Journal of Medicine 201, 201.

¹⁰ Médecines Sans Frontières, ‘Trans-Pacific Partnership Agreement – Trading Away Health’ <<http://www.msfaccess.org/spotlight-on/trans-pacific-partnership-agreement>> accessed 16 February 2016.

This paper expounds the potential threats that the TPP creates for the affordability of essential medical products in developing countries. To begin with, I propose to look at the content of the agreement's IP section in respect of (a) its data exclusivity provisions, (b) the scope of patentable subject matter, and (c) term adjustments for office delays and the potential dangers to access to medicine. Secondly, I will consider the highly criticised Investor State Dispute Settlement (ISDS) provisions of the treaty with regards to their capacity to undermine democratic principles and public policy decisions. Finally, I will examine specific threats the TPP creates for developing countries, including those that are not party to the treaty.

I. The TPP's Effect on Access to Medicine

A. The Effect of the IP Provisions

It has been argued that the high level of IP protection in the TPP promotes investment in research and the development of new medicines.¹¹ It is further argued that illicit trade of counterfeit products harms innovative corporations and that counterfeit goods, especially in the pharmaceutical sector, can directly threaten human health.¹² While this is certainly true to a certain extent, the TPP has been widely criticised by NGOs and academics for its overly rigorous patent right provisions. It is feared that the TPP regulations are capable of restricting the affordability of medical products by delaying the introduction of generic drugs to the market, thereby posing an increased threat to public health care. Patent periods provide patent holders with exclusive rights over products, basically enabling them to occupy a monopoly position in the market with a patented product. Exploiting the monopoly power, pharmaceutical corporations can demand high prices for their medical products. Once the patent period has expired however, the development of generic medicines generates competition and drives down prices. Generic medicines are commonly lower priced than patented products, and are therefore crucial to ensure the affordability of medical treatment, especially in developing countries. The price difference between original products and generics can be significant. In the case of HIV medication, for example, the average price of second-

¹¹ Inside US Trade, 'Final TPP Deal on Drug IP Has One Standard with Transitions, Leak Shows' (2015) *InsideHealthPolicy.com* <<http://insidehealthpolicy.com/>> accessed 29 November 2015.

¹² United States Trade Representative (n 2) 9.

line treatment has dropped by 75% between 2006 and 2013 due to the introduction of generics.¹³ To supply the population with original versions of a drug can therefore put a huge burden on a country's health system and on individuals who cannot rely on such a system. In developing countries this price gap can consequently make the difference between successful treatment and death due to a curable, or at least treatable, disease.

This article examines the novel patent law rules of the TPP in respect of these concerns, focussing in particular, on its increased data exclusivity provisions, its increased scope of patentable subject matter, and its compensation regulations for office delays.

i) Data Exclusivity Provisions

When first entering the market, a pharmaceutical company can apply for a patent for a drug. The registration of a patent requires the disclosure of all relevant data regarding the production of that drug, i.e. ingredients and formulas. The patentee has to consent to the publication of this information to receive a patent, enabling other corporations to conduct further research with that information.¹⁴ For a period of at least 20 years, however, the marketing rights of that product are exclusive to the patent holder. To introduce a drug to the market, a company further needs to receive marketing approval by a government, for which the patent holder has to establish that a product is reasonably safe and effective. The data necessary to receive marketing approval differs from the information needed to acquire a patent. Further research needs to be undertaken in order to establish that the product is safe for marketing. This research includes, inter alia, the disclosure of possible side effects.¹⁵ The process of marketing approval is lengthy, commonly taking place while a patent term is already running. The research results submitted for marketing approval do not have to be made publicly available according to patent requirements. A state may nevertheless require the publication of such information if no data exclusivity provisions are in existence.

¹³ Médecins Sans Frontières, 'Generic Competition Pushing Down HIV Drug Prices, But Patents Keep Newer Drugs Unaffordable' <<http://www.doctorswithoutborders.org/news-stories/press-release/generic-competition-pushing-down-hiv-drug-prices-patents-keep-newer-drugs>> accessed 15 February 2016.

¹⁴ Denoncourt J, *Intellectual Property Law: 2012-2013* (3rd ed., Routledge Revision 2012).

¹⁵ MedicineNet, 'Drug Approvals - From Invention to Market ... A 12- Year Trip' <<http://www.medicinenet.com/script/main/art.asp?articlekey=9877>> accessed 15 February 2016.

Data exclusivity provisions are a set of legal instruments preventing manufacturers of generic products from using pre-existing research results in order to prepare their own marketing approval applications for generic versions of the prior marketed goods for a certain time. In effect, these provisions are an additional form of IP protection alongside classic patent rights capable of extending patent terms and delaying the accessibility of cheaper generic drugs, as elucidated below.¹⁶ As a result, it has been argued that the increased data exclusivity provisions in the TPP might directly affect the availability of affordable drugs in developing countries across the world.¹⁷

Article 18.50.1 TPP states that if a party to the agreement requires the submission of undisclosed test or other data as a condition for marketing approval for new pharmaceutical products, no third person – i.e. a potential manufacturer of generic medicines – shall be permitted to make use of this information to market the same product for a period of at least five years, without the consent of the person that initially submitted the information. The five-year period begins on the date of the marketing approval of the new product. According to Article 18.50.1(b) the same five-year data protection period shall be applied when a Party to the treaty permits the submission of evidence of prior marketing approval of a product in another country for marketing approval. In essence, Article 18.50.1 provides that generic drug manufacturers cannot have access to existing clinical test data to develop and market a generic version of a medical product for the period of at least five years. As this information however, is vital to place a product on the market, generic manufacturers either need to wait for the information to enter the public domain, or need to conduct their own research and clinical tests. This can substantially delay the availability of competition and cheaper generic drugs or make them more expensive as the generic manufacturer will also have to refinance his research.

Article 18.50.2(a) provides that the data exclusivity provision of paragraph 1 shall further be applied

[...] for a period of at least three years with respect to new clinical information submitted as required in support of a marketing approval of a

¹⁶ Mitchell A, Voon T, and Whittle D, 'Public Health and the Trans-Pacific Partnership Agreement' (2015) 5 Asian Journal of International Law 279, 299-300.

¹⁷ Kapczynski A (n 9) 202.

previously approved pharmaceutical product covering a new indication, new formulation or new method of administration [...]

This provision provides an additional period of three years of protection for data submitted for new uses of previously marketed products. Effectively, this enables companies to extend the period of their monopoly positions by further delaying generic competition in regard to new uses of one and the same product. The provision could also encourage pharmaceutical companies not to disclose all of their data at the time of a product's first marketing approval. Instead, they could submit data regarding different uses towards the end of the patent term in order to make use of these extended data exclusivity periods. This would not only delay the marketing of generic drugs, but may also delay the availability of new treatment methods for certain diseases in an attempt to maximise future profits, even where these treatments are known to a manufacturer from the beginning.

An illustrative example for this is the well-known drug Aspirin. Best known for its use to treat mild pains, Aspirin is a multi-purpose drug which is used, *inter alia*, to treat patients who suffered from a stroke or a heart attack, as a preventative measure for patients with a high risk of getting a stroke or a heart attack, and to treat patients with colorectal cancer.¹⁸ Assuming that Aspirin was a novel drug, and that its developer knows about all its possible usages, making use of the TPP's data exclusivity provisions, a pharmaceutical company with the patent on Aspirin could apply for marketing approval for the drug for the use as a mild pain medication. In the interest of an increased monopoly position and for the sake of maximised profits, they may withhold information regarding the drug's capability to treat heart attacks, strokes, and colorectal cancer. This information is of bigger value to the corporation when disclosed at a later time. When the five-year data exclusivity period for Aspirin as a mild pain medication is about to expire, the company can then apply for another data exclusivity period in regard of marketing approval as a treatment method for heart attacks and strokes. Again, when this data exclusivity period is about to expire, a further three-year protection period can be acquired for Aspirin as a treatment for colorectal cancer. At this point, the availability of Aspirin as a treatment method for cancer has been effectively delayed by eight years.

¹⁸ Nordqvist C, 'Uses, Benefits, and Risks of Aspirin' (last updated 18 December 2017) <<http://www.medicalnewstoday.com/articles/161255.php>> accessed 27 May 2019.

Article 18.52 recognises the specific interest of corporations investing in research regarding pharmaceutical biologics, i.e. products that are or contain “a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.”¹⁹ Article 18.52.1(a) declares that in respect of new pharmaceuticals which contain biologics, Articles 18.50.1 and 18.50.3 shall be implemented with a protection period of at least eight years from the date of first marketing approval. This extended protection period of eight years is deemed necessary so as to support investment into research with biologics, which is a relatively new field of science. It is submitted that encouraging investment in this field of pharmaceutical research can create an enhanced environment for the development of improved treatment methods.²⁰

Article 18.52.1(b) provides an alternative to introducing an eight-year period of protection for biologics. A protection period of five years is considered to be sufficient if a state provides adequate market protection through other measures. Those other measures are not defined in any further detail within the treaty. However, it seems reasonable to assume that this alternative may *inter alia* refer to Article 18.50.2(a), suggesting that a party could grant an additional protection period of at least three years for new indications, formulations, or methods of administration of formerly approved products containing biologics.

The particular circumstances regarding research in the new field of biologics are explicitly recognised by Article 18.52.3 which provides that the parties to the agreement shall consult ten years after the entry into force of the treaty to review the regulations regarding biologics to accommodate for potential changes in the area.

In considering these data exclusivity provisions in the TPP, it becomes clear that the agreement aims to create a high level of protection for the monetary interests of innovative pharmaceutical corporations in order to encourage further research and development to find new treatments for conditions and diseases. Whilst these provisions are adequate for securing that goal, they certainly create a threat to public health care and the affordability of medical products by delaying generic competition.

¹⁹ Article 18.52(2) Trans-Pacific Partnership.

²⁰ US Food and Drug Administration, ‘What are “Biologics” Questions and Answers’ <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm> accessed 15 February 2016.

This adverse effect of the regulations was recognised during the negotiation processes. As a result of this realisation, various articles in the IP section of the treaty support the protection of public health. Article 18.3.1 read in conjunction with Article 18.6.1(a) provides that the obligations under the IP section shall not prevent states from taking measures to protect public health and promoting the access to medicines for all. Article 18.6.1(a) further reaffirms a party's right to determine national emergencies and other circumstances of extreme urgency in accordance with Article 5(c) of the Declaration on TRIPS²¹ and Public Health,²² commonly referred to as the Doha Declaration. Under these provisions and in accordance with Article 5(b) of the Doha Declaration a party can grant compulsory licenses, permitting a third party to make use of patented subject matter without the patent holder's consent, to manufacture generic medical products. This right of the parties to the TPP is further reaffirmed in Article 18.50.3 with direct reference to Article 18.50 paragraphs 1 and 2 in relation to the protection of undisclosed test or other data, as well as to Article 18.52 in relation to the market protection of biologics. It can therefore be presumed that Article 18.50.3 grants the parties the right to provide generic manufacturers with undisclosed test or other data when granting compulsory licences in cases of national emergencies or circumstances of extreme urgency. Such cases of national emergencies and extreme urgency are neither defined in the TRIPS agreement, nor in the TPP. However, as seen above, Article 5(c) of the Doha Declaration gives states the right to self-determine the existence of such situations.

Besides situations of national emergencies and circumstances of extreme urgency, however, the data exclusivity provisions of the TPP substantially increase the monopoly periods of new drugs.²³ As seen above, those provisions are capable of delaying the marketing approval for generic drugs, as they hamper a fast development of generic products. While generic drug manufacturers are prohibited from marketing their products during a product's patent term anyway, data exclusivity provisions further prevent generic manufacturers from conducting research using existing knowledge, effectively hampering the development of generic drugs. This may delay

²¹ Trade-Related Aspects of Intellectual Property Rights.

²² WTO, 'Declaration on the TRIPS agreement and public health'

<www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed 14 February 2016.

²³ Gleeson D and others (n 5) 22.

the availability of marketable generics even after a patent term expires. Further, Article 18.54 declares that data exclusivity rights remain in force in the event that their protection period exceeds the patent periods of a product. This provision is designed to further protect the monetary interests of innovative corporations when they have acquired a patent for a new drug, but need to undertake further research to receive marketing approval, which can often be a lengthy process in the pharmaceutical sector. For the industry and for the availability of new drugs, such a protection can be regarded as vital, as the main driver for innovative companies is generating profits from their investments in research and development. In light of public health concerns, such extended protection periods have to be regarded with scepticism. On the one hand they ensure the availability of new medicines, yet on the other hand, they delay the affordability of such products for the majority of the world's population by deferring the introduction of generic products.

ii) The Scope of Patentable Subject Matter and the Risk of Patent Evergreening

A similar risk is introduced by the TPP in regard to patent terms. When IP regulations are designed in a way that enables patent holders to acquire successive patents for new uses of an established product, they create the possibility of abusing patent rights in order to extend monopoly periods.²⁴ The TPP IP section has been criticised for potentially facilitating this so called 'patent evergreening',²⁵ which refers to the perpetuation of the benefits of patent rights using strategic methods, as patent holders can acquire new patents on existing drugs by establishing a new target group or a new method for the administration of such medical products.²⁶ As illustrated below, the TPP provides that patents shall be made available for new uses or methods of using a known product, even when those variances do not enhance the efficiency of a product.²⁷ Through this method, pharmaceutical companies can manage the disclosure of data regarding the use of a product in order to acquire successive patents for new uses, expanding their monopoly positions. This stands in direct contrast to the TRIPS

²⁴ Kilic B, Brennan H, and Maybarduk P, 'What Is Patentable Under the Trans-Pacific Partnership? - An Analysis of the Free Trade Agreement's Patentability Provisions from a Public Health Perspective' (2015) 40 Yale Journal of International Law Online 1, 4-5
<<http://www.yjil.org/docs/pub/o-40-kilic.pdf>> accessed 27 May 2019.

²⁵ McCall C, (n 8) 2451.

²⁶ Kilic B, Brennan H, and Maybarduk P (n 24) 6.

²⁷ Mitchell A, Voon T, and Whittle D (n 16) 301; Kilic B, Brennan H, and Maybarduk P (n 24) 6.

agreement which requires a product to be new and involving an inventive step in order to be patentable,²⁸ and under which it is therefore not possible for pharmaceutical companies to evergreen their patented products.

Article 28.37.1 provides that parties to the agreement

[...] shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step and is capable of industrial application.

Footnote 30 of Chapter 18 TPP further defines that the terms “inventive step” and “capable of industrial application” shall respectively be considered as being synonymous with the terms “non-obvious” and “useful”. This paragraph is equivalent to the respective TRIPS provision to be found in Article 27(1) TRIPS.

The novelty of the TPP’s patent regime however, derives from Article 18.37.2 which requires parties to make patents available

[...] for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit those processes to those that do not claim the use of a product as such.

This arrangement constitutes a substantial extension of international patent law regulations, contravening the international patent regime provided by TRIPS, and undermining both Article 27(1) TRIPS as well as Article 18.37.1 of the TPP itself. By introducing the patentability of new uses, new methods of using, and new processes of using known products, paragraph 2 effectively abrogates the purpose of those provisions to only award patents for new products – it basically eliminates the need for an inventive step. By introducing the possibility of constructing evergreening patents, Article 18.37.2 creates an incentive for the pharmaceutical industry to efficiently manage the life circle of products, effectively extending patent periods.²⁹ To reach this goal, companies may consider a similar strategy as with the disclosure of data for marketing approval. Thus, information about medical products, known when a product was patented for the first time, may not be disclosed until a later stage of a patent period in order to maintain the opportunity of receiving a second patent

²⁸ Article 27(1) TRIPS.

²⁹ Gleeson D and others (n 5) 14.

term by establishing new uses, methods of using, or processes of using at the end of that product's original patent term. Such life cycle management arrangements not only affect the introduction of cheaper generic medicines due to the extended durations of patent protections. They also comprise the risk that additional or improved procedures of treating diseases and conditions will enter the market with serious delays, compromising the health of those affected by these conditions. Reconsidering the above example of Aspirin as a multi-purpose drug, a company could apply for a first patent for Aspirin as a mild pain medication. At the end of the 20-year patent period, the company then can – according to the TPP provisions – apply for a patent for Aspirin's new use as a heart attack and stroke treatment, acquiring a second patent term of another 20 years. A third patent period can then be acquired for its new use as a treatment for colorectal cancer. The availability of Aspirin as a treatment for cancer would therefore be delayed by 40 years, and the availability of generic competition would be delayed by 60 years, giving the patent holder a monopoly position on the market with all its detriments for public health. Exploiting the monopoly power, pharmaceutical corporations can demand high prices for their patented medical products. The main threat of the provisions in Article 18.37.2 can therefore be seen in the risk that when human health is balanced against financial interests, human health will most certainly draw the short straw.

To diminish this risk, Articles 18.40 and 18.41 TPP reaffirm a party's right to introduce exceptions from the patent right protection under certain circumstances. Article 18.40 TPP declares

A Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owner, taking account of legitimate interests of third parties.

This is a vague provision as it does not define the terms “unreasonable conflict” and “legitimate interests of third parties”. When read in conjunction with Article 18.41, which provides that nothing in the IP chapter shall limit rights and obligations under Article 31 TRIPS however, it should be interpreted to mean that in cases of national emergencies or circumstances of extreme urgency public health constitutes a legitimate interest of third parties, and that restrictions of the exploitations of patents in such situations are not deemed unreasonable.

A further instrument to protect public health can be found in Article 18.37.3(a) TPP, which grants parties the option to exclude “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” from patentability.³⁰ This means that the mere technique of how a condition or disease is treated cannot be patented.

While the TPP created the incentive to generate evergreening patents, the agreement also introduced certain measures to balance the risks posed by this by providing exceptions to protect human health. How far states will exert their rights under those provisions in the future remains to be seen. Concerns have been raised that states might be reluctant to apply such exceptions so as not to incur liability under the ISDS clauses provided by the TPP as scrutinised below.

iii) Term Adjustments for Pharmaceutical Patents to Compensate for Office Delays

The third controversial issue of the TPP’s IP regulations is the compensation for unreasonable office delays in granting patents or marketing approval for pharmaceutical goods. Since a patent term usually begins at the time of application a delay in granting can lead to a significant curtailment of the period in which a patentee can actually make use of it. The same is true when a patent has already been granted but marketing approval is being delayed. The agreement includes measures to adjust patent terms for affected products, further delaying the availability of generic medicines.³¹

Article 18.46.1 states that parties to the treaty shall avoid unreasonable or unnecessary delays in processing patent applications. Similarly, Article 18.48 provides the same provision in relation to marketing approval applications for pharmaceutical products. In the case that unreasonable delays occur in the issuance of a patent or there is an unreasonable curtailment in the marketing approval process, Article 18.46.3 declares that parties shall make available adjustments to the patent term to compensate for unreasonable delays. Similarly, Article 18.48.2 provides for patent term adjustments to compensate for unreasonable curtailments. While such patent term adjustments seem fair from the point of view of innovative pharmaceutical companies, they could

³⁰ Article 18.37.3(a) Trans-Pacific Partnership.

³¹ Mitchell A, Voon T, and Whittle D (n 16) 302-303; Gleeson D, Lopert R, and Reid P, ‘How the Trans Pacific Partnership Agreement could undermine PHARMAC and threaten access to affordable medicines and health equity in New Zealand’ (2013) 112 Health Policy 227, 231.

delay the introduction of affordable medicines. Article 18.46.4 however, reduces these concerns by defining that an unreasonable delay in the issuance of a patent only exists when more than five years have passed since an application has been filed. There is no similar definition for unreasonable delays of marketing approval applications. Article 18.48.3 nevertheless grants parties the option of implementing conditions and limitations to the compensation rules, as long as they continue to give effect to these compensations.

While it seems just to compensate patent holders for unreasonable office delays, it is recognised that patent term adjustments mainly burden people with diseases or conditions who cannot afford adequate treatment with the original product.³² It is therefore submitted that the patent term adjustment measures in the TPP are not an adequate instrument to compensate for unreasonable delays. The fault for such delays lies within the offices of the treaty's members, and thus so too should the liability.

B. The Investor State Dispute Settlements and Its Effects

Chapter 9 of the TPP regulates the protection of foreign investments, including an Investor State Dispute Settlement (ISDS) system. This system enables private investors to bring claims directly against a state for breaching treaty regulations. An investor does not need to rely on his home state to bring an action against another state, as is usually the case in international law. This is important so as to encourage foreign investments, as states are sometimes reluctant to bring an action against other states, in the interest of maintaining positive political relationships. ISDS claims are usually heard by arbitral tribunals instead of domestic courts, a process which was deemed necessary in the past given that developing countries often do not have a fair working judicial system.³³ Introducing ISDS clauses and arbitral proceedings was subsequently seen as an encouragement of foreign investment with the possibility of supporting economic growth and development in these countries.³⁴

There is controversy, however, over whether such claims against states should be heard outside of national courts. On the one hand, it is argued that this is a necessary means

³² McCall C (n 8) 2450.

³³ Mitchell A, Voon T, and Whittle D (n 16) 282-283.

³⁴ *ibid* 286; de Mestral A, 'Investor-State Arbitration between Developed Democratic Countries' (September 2015) CIGI Investor-State Arbitration Series, Paper No. 1, 1.

as arbitration awards are commonly easier to enforce than national judgements.³⁵ On the other hand, it is often criticised that arbitration hearings are conducted by groups of corporate appointed lawyers,³⁶ with a lack of neutrality and a lack of expertise in certain public interests like public health care. The lack of transparency in such arbitration proceedings in general has also been the subject of criticism.³⁷ A further controversy regarding ISDS clauses is that they give private investors the possibility of suing sovereign states over democratic public policy decisions, enabling private investors to challenge any of those policies, disregarding the public interest.³⁸ As a result, whenever an investor claims to have reduced profits or to have suffered a loss in connection with a party allegedly breaching a TPP regulation, arbitral proceedings would be the likely consequence.³⁹ Such a system may create an environment in which the corporate interests of private investors are privileged over broader public interests.⁴⁰ This poses the risk that the sovereignty of a state is restricted, and that a part of such power is transferred to multinational corporations.⁴¹ It has therefore been indicated that these shifts in sovereign power directly challenge the rights of states to self-regulation.⁴²

Nevertheless, it must be acknowledged that such challenges to national policies can only occur when a state has breached its treaty obligations in the first place. Furthermore, it is noteworthy that public policies in democratic countries are also frequently challenged in front of national courts when an individual or a company argue that a certain policy creates obstacles to their rights.⁴³ It is submitted however, that domestic courts commonly have a higher expertise in assessing the legal foundations and justifications of public policies, as well as a democratic perspective and an interest in such policies, which arbitral tribunals do not have. Considering the possible restriction of the sovereignty of national governments, academics and

³⁵ Malawer S, 'Looking at Dispute Resolution in the Trans-Pacific Partnership' (2015) 254 *New York Law Journal* 4.

³⁶ Beard M (n 6) 41.

³⁷ Mitchell A, Voon T, and Whittle D (n 16) 284; de Mestral A (n 34) 12.

³⁸ Ruckert A, Schram A, and Labonté R (n 4) 249.

³⁹ Beard M (n 6) 41; Mitchell A, Voon T, and Whittle D (n 16) 284.

⁴⁰ Mitchell A, Voon T, and Whittle D (n 16) 284.

⁴¹ Beard M (n 6) 42.

⁴² de Mestral A (n 34) 14.

⁴³ *ibid* 14-15.

NGOs have raised concerns that ISDS clauses as found in the TPP are inappropriate and anti-democratic.⁴⁴

In addressing the concerns regarding the impartiality of arbitrators, it is submitted that they have to be considered on a case by case basis. It cannot be generalised that arbitrators are biased and, *vice versa*, that all national courts are completely neutral. Prejudice can exist anywhere, but among professionals, problems associated with prejudice can generally be regarded as exceptional. To create a balanced and fair working system, Article 9.21.1 provides that an arbitration tribunal consists of three arbitrators. Whilst the disputing parties have the right to mutually agree on a different way of procedure, the general rule requires each party to appoint one arbitrator. Those arbitrators then select a third arbitrator by agreement, who will be the neutral chair of the arbitration proceedings. This system grants both parties equal rights while ensuring impartiality in the arbitration.

A main concern surrounding arbitration proceedings in general is that according to the current international standard, arbitration hearings are conducted in secret.⁴⁵ Particularly when the subject matter of a dispute concerns public interests, closed sessions are highly controversial.⁴⁶ The TPP admittedly steps away from the international norm by providing enhanced transparency provisions in Article 9.23. As analysed by Sonja Heppner, the TPP regulation expediently improves arbitration hearings, by introducing the requirement that those hearings are open to the public.⁴⁷

However, Article 9.23.2, provides an exception to this new rule when a hearing requires a party to disclose protected information. In such instances, an arbitration “tribunal shall make appropriate arrangements to protect such information from disclosure which may include closing the hearing for the duration of the discussion of that information.”⁴⁸ According to Article 9.23.4(d) the tribunal has the right to determine whether information qualifies as protected information. The possibility to temporarily close a hearing to the public is necessary to protect confidential information and in so far as such closures are adequately restricted to exceptional

⁴⁴ *ibid* 4-5; Beard M (n 6) 43.

⁴⁵ Beard M (n 6) 42.

⁴⁶ de Mestral A (n 34) 11.

⁴⁷ Heppner S, ‘A Right of Public Access to Investor-State Arbitral Proceedings?’ (09 December 2015) <<http://kluwerarbitrationblog.com/2015/12/09/a-right-of-public-access-to-investor-state-arbitral-proceedings/>> accessed 15 January 2016.

⁴⁸ Article 9.23.2 Trans-Pacific Partnership.

circumstances they constitute an appropriate procedure. Therefore, the transparency provision of the TPP is not only a welcome measure by which to establish a fair environment for arbitral hearings. It can further help to establish arbitral precedents and hence help to shape investment law for the future by publication of the arbitral findings and therefore creating references for future arbitrations.⁴⁹

In relation to public health, the major problem of introducing ISDS mechanisms to the TPP is the prospect of states being sued over public health policies and regulations that are capable of restricting IP rights of multinational corporations. This may lead to a 'regulatory chill'.⁵⁰ Governments may express a reluctance to introduce appropriate measures to protect public health if there is a realistic risk of facing expensive litigation with the potential of becoming liable to extensive payments in damage compensations.⁵¹ This may prove true for developing countries in particular, which might face difficulties defending themselves due to lack of funds. Armand De Mestral has objected to this argument claiming that proof for such allegations is very scarce. However, it can be seen by the example of Uruguay applying for funds from Bloomberg Philanthropies and the Bill and Melinda Gates Foundation to defend itself in an arbitral proceeding against Phil Morris International, that expensive arbitrations create real obstacles for developing countries.⁵²

Whether or not the TPP ISDS system will lead to such a 'regulatory chill' can only be determined in the future. However, the TPP provides regulations mitigating the risk in consideration of public health. First, there are the above-mentioned exceptions in the IP section of the agreement which reaffirm a party's right to protect public health according to the TRIPS agreement and the Doha Declaration. Further, Article 9.15 provides that

Nothing in this chapter shall be construed to prevent a Party from adopting, maintaining or enforcing any measure otherwise consistent with this Chapter that it considers appropriate to ensure that investment activity in its territory is undertaken in a manner sensitive to environmental, health or other regulatory objectives.

⁴⁹ Heppner S (n 47).

⁵⁰ Ruckert A, Schram A, and Labonté R (n 4) 250.

⁵¹ *ibid*; Kapczynski A (n 9) 202.

⁵² de Mestral A (n 34) 16.

Whether this provision is capable of reducing the fear of expensive litigation and the concomitant risk of ‘regulatory chills’ is not clear. Although the regulation protects the public health interests of a state, scrutinising whether or not a state acted according to this rule remains in the authority of an arbitral tribunal.

To summarise, the main threat of the intensified patent law provisions of chapter 18 TPP is that states have to award increased patent terms and data exclusivity periods thereby enabling pharmaceutical corporations to effectively control the life cycle of patents. This can occur through management of the disclosure of relevant information about medical products, exhausting to the fullest extent the new regulations regarding the patentability of new uses, new methods of using, and new processes of using known products. While states have the exceptional right to introduce measures restricting the exclusive rights granted by patents, awarding compulsory licenses in cases of national emergencies and other circumstances of extreme urgency, governments, especially of developing nations, may be reluctant to make proper use of those exceptions, as the circumstances of such situations are not sufficiently defined. Although Art 5(c) of the Doha Declaration provides that each member to the TRIPS agreement has the right to self-determine what constitutes a national emergency or circumstance of extreme urgency, it must be recognised that chapter 9 TPP gives private investors the opportunity to challenge basically any national policy. This constitutes a direct challenge to human rights protection, as human health and human life might be balanced against monetary interests, which stands in a contrast with the purposes of the human right to health and the human right to life.

With regard to essential medicines, monopoly powers and concomitant high drug prices combine to create the risk of rationing of medical treatment.⁵³ The delayed introduction of cheaper medicines, supported by the novel regulations of the TPP’s IP section, not only represents an obstacle to the adequate access to essential drugs, but might further induce the unaffordability of certain drugs for major sections of human populations.⁵⁴

⁵³ Inside US Trade (n 11).

⁵⁴ Beard M (n 6) 42.

II. The Potential Spill-Over Effect of the TPP

The annexes of the TPP provide only limited exceptions regarding the adoption of the agreement's regulations in certain member states, so that generally speaking, all parties to the treaty have to introduce the same standards irrespective of their level of development and differences in poverty or wealth between those countries.⁵⁵ However, the TPP's patent regime may not only disadvantage less wealthy countries that are party to the treaty. There exists a realistic risk that spill-over effects broaden the reach of its regulations,⁵⁶ adversely affecting the distribution of essential medicines in other developing countries in the Pacific region and around the world.

It has been recognised that the TPP is capable of setting a new baseline for future trade treaties, becoming a model agreement and therefore further extending the geographical scope of its regulations.⁵⁷ There is a reasonable possibility that the TPP can form a starting point for future negotiations of treaties,⁵⁸ possibly setting a standard for future regional trade agreements and potentially even for one at WTO level.⁵⁹ The Transatlantic Trade and Investment Partnership (TTIP), currently under negotiation between the USA and the EU, already follows a very similar approach and the successful conclusion of the TPP could provide a template for the future TTIP scheme.

The TPP is designed in a way that not only offers the possibility for other countries to join the treaty,⁶⁰ but also creates indirect incentives pushing those states to do so. It creates an incentive for multinational corporations and private investors to locate foreign investments in countries that are party to the agreement as they will have established certain securities to protect such investments. A negative spill-over effect for other countries can therefore especially be found in diversions of trade investments to party states.⁶¹ To remain part of regional and international trade, those countries not party to TPP need to provide similar protection measures so as to attract foreign investment, meaning that they have to implement potentially detrimental regulations

⁵⁵ Inside US Trade (n 11).

⁵⁶ Narayanan B, Vardhana Singh H, and Ciuriak D, 'Quantifying TPP and TTIP Spillovers on India' (2016) <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2680185> accessed 28 January 2016.

⁵⁷ Mitchell A, Voon T, and Whittle D (n 16) 280.

⁵⁸ *ibid.*

⁵⁹ Gantz D, 'The TPP and RCEP: Mega-Trade Agreements for the Pacific Rim' (2016) 33 *Arizona Journal of International and Comparative Law* 57, 60.

⁶⁰ Kapczynski A (n 9) 202.

⁶¹ Kilic B, Brennan H, and Maybarduk P (n 24).

to keep pace with international trends. Since nations not party to the TPP are therefore affected by the negative effects of the treaty,⁶² it lies in their interest to join the agreement in the future in order to likewise access its benefits, despite negative consequences. Consequently, a number of other countries in the Pacific region had already expressed their interest in joining while the TPP was still under negotiation.⁶³ The US are anticipating that members of the Asia Pacific Economic Cooperation (APEC), such as China, Indonesia, Korea, the Philippines and Thailand will accede in the future.⁶⁴

As the countries involved in the TPP are host to some of the world's most influential multinational enterprises, it is likely that potential spill-over effects of the treaty will have a far reach on global trade, as those corporations have the power to set new standards in international trade.⁶⁵ For example, as one of the world's largest economies, India – which currently is not a party to the TPP – has strong economic connections with many of the TPP member states.⁶⁶ It is estimated that while they are not parties to the treaty, China and India will be the main 'losers' of the TPP.⁶⁷ It can therefore be anticipated that India will consider appropriate measures to reduce any negative effects on its economy,⁶⁸ which may include potentially joining the partnership.⁶⁹ While India's current patent system provides patents on new medical products in accordance with its obligations under the TRIPS agreement,⁷⁰ section 3(d) of India's Patent Act explicitly excludes the patentability of new forms and new uses of known products if such novelties do not enhance the efficacy of known products.⁷¹ By not comprising the possibility of evergreening patents, this provision effectively prevents companies from exploiting patent regulations through adjusting a patent's life circle management.⁷² While India has traditionally been reluctant to provide higher IP protection standards, economic pressure might force a reconsideration of this stance in the future. India's pharmaceutical industry has been crucial in providing developing

⁶² *ibid.*

⁶³ Mitchell A, Voon T, and Whittle D (n 16) 280.

⁶⁴ Gantz D (n 59) 60.

⁶⁵ Kilic B, Brennan H, and Maybarduk P (n 24).

⁶⁶ *ibid.*

⁶⁷ *ibid.*

⁶⁸ *ibid.*

⁶⁹ McCall C (n 8) 2450.

⁷⁰ Kapczynski A (n 9) 201.

⁷¹ Kilic B, Brennan H, and Maybarduk P (n 24) 5.

⁷² *ibid.*

countries with adequately priced generic antiretroviral (ARV) medicines for the treatment of HIV/AIDS. The possibility of India providing such kinds of generics is already hampered by the implementation of the TRIPS agreement.⁷³ Therefore, changing India's patent regime so as to align with the TPP IP regulations would imply a further major obstacle for the distribution of adequately priced and affordable medical products in developing countries, as currently India can be seen as one of the world's main sources for cheaper generic medicines.⁷⁴

III. Conclusion

After scrutinising the regulations provided by the TPP, it becomes apparent that many of the apprehensions expressed before the agreement was concluded are well founded. In particular, the IP section of the treaty gives rise to concerns regarding the future distribution of affordable medicines. The newly introduced patentability of new uses, new methods of using, and new processes of using known products runs the high risk of effectively delaying the introduction of generic drugs to the market by extending patent terms and data exclusivity protection periods. Additionally, it is reasonable to assume that pharmaceutical corporations will delay the disclosure of essential research findings regarding the application of new medical products as a means of extending the life cycle of patent periods for such products, which can lead to a situation where enhanced methods of treating diseases and conditions are only made available after substantial delays. Therefore, it can be argued that the TPP's IP system considerably aggravates the international patent regime by introducing the possibility of evergreening patents.

While it should be recognised that member states still have an opportunity to introduce measures for protecting public health, inter alia by applying exceptions in cases of emergencies, those options are somewhat constrained by the TPP's investment protection clauses. The ISDS provisions found in the investment chapter of the agreement enable private investors and corporations to challenge basically any policy

⁷³ Waning B, Diedrichsen E, and Moon S, 'A Lifeline to Treatment: The Role of Indian Generic Manufacturers in Supplying Antiretroviral Medicines to Developing Countries' (2010) 13 *Journal of the International AIDS Society* 35.

⁷⁴ McCall C (n 8) 2450.

by claiming that such a policy creates an obstacle to their investment by breaching a treaty regulation.

Arbitrational proceedings for international investment disputes already existed before the TPP was negotiated. In this regard it has to be recognised that the ISDS system provided by the agreement is not as bad as had been anticipated prior to its conclusion. It has to be acknowledged that the transparency regulations provided by Article 9.23 TPP are a welcome improvement, capable of taking the appropriateness of the system of international arbitration a step further.

Nevertheless, the mere possibility that private investors can challenge a state's public health policy – which is in the interest of its whole population – can be seen as an obstacle that may lead to a 'regulatory chill'. The criticism that such a regulation may be anti-democratic is justified as it means that investors can challenge measures adopted by democratically elected governments outside their national courts.

Despite the limited applicability of the TPP to its member states, it is a realistic threat that an agreement of such a magnitude can extend negative effects to other countries as well. Those states may be pressured into implementing similar regulations to those provided by the TPP in order to attract foreign investment and for remaining players in regional and international trade. As the TPP is a platform agreement, more countries, including developing countries, are being encouraged to join the treaty which further expands the applicability of its regulations. As the TPP might, moreover, become a model for future trade agreements, the negative consequences of the partnership may find their way into other treaties as well, additionally expanding their geographical scope.

Finally, if India should join the TPP, the world might lose one of its most important distributors of essential generic medicines. This could potentially have devastating effects on the affordability of adequate treatment for a majority of the population of developing countries around the world. In this regard, it is fair to say that when the advantages the TPP provides for the development of new medical products are balanced against the constraints it constitutes for the affordability of essential medicines, the negative effects on public health care are likely to weigh more heavily.

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